Table of Contents

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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2009

or

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

Commission File Number 001-33103

CADENCE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**41-2142317**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

12481 High Bluff Drive, Suite 200
San Diego, California 92130
(858) 436-1400
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, $0.0001 par value per share	**NASDAQ Global Market**
(Title of class)	**(Name of exchange on which registered)**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. 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 ☒ (Do not check if a smaller reporting company)	Non-accelerated filer ☐	Smaller reporting company ☐

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2009, the last business day of the Registrant's second fiscal quarter, reported on the NASDAQ Global Market, was approximately $245,681,033. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the Registrant's outstanding common stock have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes. The Registrant does not have any non-voting common equity securities.

As of February 28, 2010, there were 50,512,429 shares of the Registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates certain information by reference from the Registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the Registrant's 2010 Annual Meeting of Stockholders, which is scheduled to be held on June 16, 2010. Such Definitive Proxy Statement will be filed with the Commission not later than 120 days after the conclusion of the Registrant's fiscal year ended December 31, 2009.

Table of Contents

Forward-Looking Statements

You should read the following together with the more detailed information regarding our company, our common stock and our financial statements and notes to those statements appearing elsewhere in this document or incorporated by reference. The Securities and Exchange Commission, or SEC, allows us to "incorporate by reference" information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this Annual Report on Form 10-K, or Annual Report.

This Annual Report and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "hopes," "may," "will," "plan," "intends," "estimates," "could," "should," "would," "continue," "seeks," "pro forma," or "anticipates," or other similar words (including their use in the negative), or by discussions of future matters such as the development of new products, technology enhancements, possible changes in legislation or the regulations that impact our business and other statements that are not historical. These statements include but are not limited to statements under the captions "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading "Item 1A. Risk Factors" and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

Table of Contents

CADENCE PHARMACEUTICALS, INC.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2009

Table of Contents

PART I

Item 1. *Business*

Company Overview

We are a biopharmaceutical company focused on in-licensing, developing and commercializing product candidates principally for use in the hospital setting. We currently have rights to one product candidate, Ofirmev™, a proprietary intravenous formulation of acetaminophen for the management of pain and reduction of fever in adults and children. We in-licensed the exclusive United States, or U.S., and Canadian rights to Ofirmev from Bristol-Myers Squibb Company, or BMS, which sells this product candidate in Europe and other markets for the treatment of acute pain and fever under the brand name Perfalgan®.

We submitted a New Drug Application, or NDA, for Ofirmev to the Food and Drug Administration, or FDA, in May, 2009. The NDA was accepted for filing in July 2009, and designated for priority review. Pursuant to Prescription Drug User Fee Act, or PDUFA, guidelines, the FDA was expected to complete its review and provide an action letter with respect to the NDA in November 2009; however, the agency instead indicated that its review would be extended for up to three additional months, resulting in a new PDUFA goal date in February 2010. On February 10, 2010, we received a complete response letter from the FDA, which stated that the NDA could not be approved in its present form due to deficiencies with respect to good manufacturing practices observed during the agency's inspection of the facilities of our third party manufacturer, which was completed on February 5, 2010. In the complete response letter, the FDA did not indicate that any additional clinical trials were required in order to approve the NDA for Ofirmev and did not cite any safety or efficacy deficiencies. On February 18, 2010, our third party manufacturer submitted a response letter concerning the good manufacturing practice observations to the FDA. As soon as the inspectional observations are resolved, we plan to re-submit the NDA for Ofirmev.

If approved, we believe that Ofirmev will fulfill significant unmet needs for the management of pain and reduction of fever in children and adults. We also believe that the hospital pharmaceuticals market is both concentrated and underserved, and we are preparing to build our own hospital-focused sales force to promote Ofirmev to this market, along with any other product candidates we may acquire in the future. We intend to build a leading franchise in the hospital setting, continuing to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations.

We were incorporated under the laws of the State of Delaware in May 2004. Our principal executive offices are located at 12481 High Bluff Drive, Suite 200, San Diego, California 92130 and our telephone number is (858) 436-1400. Information about the company is also available at our website at www.cadencepharm.com, which includes links to reports we have filed with the Securities and Exchange Commission, or SEC, which are available free of charge. The contents of our website are not incorporated by reference in this Annual Report on Form 10-K. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. Information on the operation of the Public Reference Room is available by calling the SEC at 1-800-SEC-0330. These reports may also be accessed free of charge via the SEC website, www.sec.gov.

The U.S. Patent and Trademark Office has issued a Notice of Allowance in connection with our intent-to-use trademark application for the mark Cadence™, and we have applied for U.S. trademark registration of Ofirmev™. This report also contains trademarks of others, including Caldolor®, Darvocet®, DepoDur®, Percocet®, Perfalgan®, Toradol®, Tylenol®, Tylenol Codeine 3 McNeil®, Ultram®, and Vicodin®.

Our Business Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of proprietary pharmaceuticals principally for use in the hospital setting. Our near-term

strategy is to focus on obtaining FDA approval for and commercializing Ofirmev. Longer-term, our strategy is to in-license, acquire, develop and commercialize additional product candidates that are in late-stages of development, currently commercialized outside the U.S. or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations. Specifically, we intend to:

- *Obtain regulatory approval for our product candidate, Ofirmev* We expect to re-submit an NDA for Ofirmev as soon as possible following the successful resolution of the deficiencies noted during the FDA's recent inspection of our third party manufacturer's facility. We do not anticipate that we will need to conduct any additional clinical trials in order to obtain approval of the NDA for Ofirmev.
- *Prepare to successfully launch and expand the sales of Ofirmev* We plan to continue our preparations for launching Ofirmev upon NDA approval. These preparations include finalizing agreements with wholesalers for the distribution of Ofirmev to hospitals, completing the development of our internal commercialization infrastructure and systems, and developing promotional and medical education materials that will be used by our sales force and medical science liaisons, respectively, to inform and educate hospital-based physicians who treat patients with mild to severe pain and fever. These physicians include anesthesiologists, surgeons, intensivists, internists, emergency medicine physicians, and others.
- *Build a highly leverageable sales organization targeting hospitals* We are continuing to develop a commercial sales and marketing organization that will focus on promoting Ofirmev to hospitals in the U.S. To date, we have hired a highly experienced sales management team and, upon the approval of Ofirmev, we are prepared to hire approximately 150 hospital sales specialists. Because the number of institutions comprising the hospital marketplace is relatively limited, we believe that we can successfully promote Ofirmev with our own sales force by focusing on the relatively small number of these institutions that account for a substantial portion of the prescribing activity. The concentrated nature of this market creates the opportunity for significant marketing synergies, and we intend to ultimately leverage our sales force with multiple products across multiple therapeutic categories in the hospital. Outside the U.S., we intend to establish strategic partnerships for the commercialization of Ofirmev, along with any other product candidates we may acquire in the future, in areas where we have commercialization rights.
- *Expand our product portfolio through acquiring or in-licensing additional late-stage, hospital-focused products with well-understood risk profiles* We will seek additional opportunities to acquire or in-license products to continue to exploit our commercial and development capabilities. We believe that our focus on the hospital market enables us to evaluate a broad range of products across multiple therapeutic areas for possible acquisition. To reduce the time to market and the risks and costs of clinical development, we will continue to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations.
- *Pursue additional indications and commercial opportunities for Ofirmev and future product candidates* We will seek to maximize the value of Ofirmev and any other product candidates we may in-license, acquire or develop. These activities may include pursuing additional indications and commercial opportunities for Ofirmev and any other product candidates we may acquire.

Product Candidates

Ofirmev™ Product Overview

As soon as possible following the resolution of deficiencies at our third party manufacturer's facility, we plan to re-submit an NDA for Ofirmev, our proprietary intravenous formulation of acetaminophen, seeking approval for the use of this product candidate for the management of pain and reduction of fever in adults and children.

In its oral form, acetaminophen is the most widely used drug for the treatment of pain and fever in the U.S. Acetaminophen was discovered in the late 19th century and was made available for sale in 1955, when it was

introduced in the U.S. under the brand name Tylenol. Acetaminophen is currently available in over 600 combination and single-ingredient prescription and over-the-counter medicines, including tablet, caplet, orally-dosed liquid suspension, powder and suppository forms for both adults and children. Despite the broad usage of acetaminophen, there is no intravenous formulation currently available in the U.S. for patients who are unable to take medications by mouth, require faster onset of pain relief or fever reduction, or for whom it is otherwise more convenient to receive an injectable analgesic.

Our licensor, BMS, currently markets this proprietary intravenous formulation of acetaminophen for the treatment of acute pain and fever in Europe and several other markets outside the U.S., where it is known as paracetamol and marketed under the brand name Perfalgan. We in-licensed the exclusive U.S. and Canadian rights to Ofirmev from BMS in March 2006.

Pain Management

Despite major improvements in surgical techniques and the introduction of novel drugs, the overall treatment of post-operative pain has not substantially improved over the last 20 years. According to the industry research group Datamonitor, up to 75% of patients report inadequate pain relief after surgery. Inadequate treatment of pain may lead to a variety of symptoms, including anxiety, depression, insomnia, fatigue, decreased appetite, nausea and vomiting. Decreased mobilization may also result from the inadequate treatment of pain, which may increase the risk of deep venous thrombosis, reduced lung tidal volume, and partial collapse or incomplete inflation of the lungs, as well as potentially prolonging hospital stays. All of these factors have the potential to significantly impact patient care and create additional costs for hospitals.

Drugs used to treat pain are collectively known as analgesics. Injectable formulations of analgesics are typically used when patients are unable to take medications by mouth, would benefit from a faster onset of analgesia, when other administration routes are medically contraindicated, or when it is more convenient to administer drugs in injectable form. Hospitalized patients may be unable to take medications by mouth for a variety of reasons, including gastric or intestinal dysfunction, pre-operative or pre-procedural restrictions, sedation, mental status changes or neurological conditions that increase the risk of aspiration, nausea or vomiting, or as a result of conditions that make swallowing painful, such as oral or esophageal infections, inflammation or ulceration. Only two classes of injectable analgesics are available in the U.S. for the treatment of acute pain, opioids and non-steroidal anti-inflammatory drugs, or NSAIDs.

Opioids have been used as analgesics for over 2,000 years and continue to be the mainstay of post-operative pain management. Opioids interact with certain receptors in the central and peripheral nervous system to produce beneficial effects, which include analgesia, sedation and euphoria. A range of naturally occurring, semi-synthetic and synthetic opioids are available for intravenous use, including morphine, fentanyl, hydromorphone, meperidine, sufentanil, and alfentanil.

Opioids, however, may also be associated with a variety of unwanted side effects when used to treat acute pain, including respiratory depression, excessive sedation, nausea, vomiting, constipation, urinary retention, itchiness, chest wall rigidity, cognitive impairment, and seizures. Respiratory depression may lead to death if not monitored closely. Side effects from opioids have been demonstrated to reduce patients' quality of life. Opioid use may prolong a patient's stay in the post-anesthesia care unit or ambulatory surgical facility, as well as a patient's overall length of stay in the hospital, as a result of opioid side effects and the need to administer additional medications or treatments to resolve opioid side effects. Studies have demonstrated that surgical costs may be increased by opioid use, not only due to additional personnel time required to handle and dispose of these controlled substances, but also as a result of costs associated with treating opioid-related side effects, including the potential need for the patient to remain in the hospital for an extended period of time.

The only non-opioid intravenous analgesics currently available in the U.S. are the NSAIDs Toradol (ketorolac tromethamine), a generic form of which is also available in the U.S. from a number of manufacturers,

and Caldolor (ibuprofen), which was approved by the FDA in mid-2009 for the treatment of mild to moderate pain in adults, and moderate to severe pain in adults as an adjunct to opioid therapy. Neither of these products are currently indicated for use in pediatric patients. NSAIDs act as non-selective inhibitors of the enzyme cyclooxygenase, inhibiting both the cyclooxygenase-1, or COX-1, and cyclooxygenase-2, or COX-2, enzymes. The inhibition of COX-2 produces an anti-inflammatory effect resulting in analgesia. Since NSAIDs do not produce respiratory depression or impair gastrointestinal motility, they are considered to be useful alternatives or adjuncts to opioids for the relief of acute pain.

However, the use of NSAIDs is limited in the post-operative period due to their potential to cause increased bleeding. Non-specific NSAIDs, such as ketorolac, block both COX-1 and COX-2, which results in an anti-inflammatory effect but also reduces platelet aggregation and increases gastric irritation, creating the potential for gastric ulcers and bleeding. Additionally, renal toxicity and the potential for increased cardiovascular events further limit the post-operative use of NSAIDs. All NSAIDs carry a boxed warning for a number of side effects. A boxed warning is the strongest type of warning that the FDA can require for a drug and is generally reserved for situations where prescribers should be aware of the potential for adverse drug reactions that can cause serious injury or death.

Fever Reduction

Fever is an increase in internal body temperature above its average normal value. A significant fever is usually defined as an oral temperature of greater than 101.5 degrees Fahrenheit (38 degrees Centigrade). Fever is typically a sign of the body's response to an underlying infection, disease process or allergic reaction. Very high fevers may cause hallucinations, confusion, irritability, convulsions or death.

Hospitalized patients are at especially high risk for developing fever due to the prevalence of infections, whether community- or hospital-acquired, and as a result of invasive procedures and treatments that may cause fevers. Surgery is the most common predisposing factor for fever in the hospital setting, with published incidence rates ranging from 14% to 91% of post-operative patients. Infections such as surgical wound infections, urinary tract infections, and pneumonia are the most common causes of post-operative fevers. However, deep venous thrombosis, pulmonary emboli, myocardial infarction, transfusions of blood products, and medications are also important potential causes of post-operative fever. Many patients also enter hospitals and emergency rooms with fevers that caused by infections or complications from an underlying disease or medical condition. While the origin of a fever is often unknown, treatment to reduce fever will typically be given even if the cause cannot be determined.

Fever is also the most common reason parents bring their children to hospital emergency rooms. Pediatric fever is particularly worrisome, as approximately 4% of children under age five and nearly one in five children born prematurely experience fever-induced seizures, or febrile seizures. The signs of febrile seizures, which occur when a child's temperature rises or falls rapidly, include loss of consciousness and convulsions.

Acetaminophen, ibuprofen and aspirin are the most commonly used oral medications to treat fever. Caldolor (intravenous ibuprofen) is not approved for the treatment of fever or pain in children. Aspirin is contraindicated in children and teenagers with viral infections due to the risk of acquiring Reye's syndrome, a potentially fatal disease.

Treating fever in a hospitalized patient with oral medication may be difficult or not feasible due to the severe nausea and vomiting that often accompany a high fever, or because the patient is unconscious, sedated, fasting or experiencing gastrointestinal dysfunction. Oral medications are also precluded in patients on a restricted oral intake regimen due to a concomitant medical condition or upcoming medical procedure. In the U.S., neither acetaminophen nor aspirin are currently available in intravenous dosage forms. While rectal delivery of these medications is sometimes possible, drug absorption using this method may be highly variable, resulting in the potential for inadequate levels of efficacy. Rectal delivery is further complicated if the drug is

expelled with a bowel movement, which leads to difficulty determining the amount of medication delivered. This is a particular issue for neonates and infants. As a result, pediatric dosing guidance for rectally administered acetaminophen calls for higher loading doses and higher daily maximum doses than for orally administered acetaminophen, which may place some neonates and infants at risk for toxicity if the drug is absorbed at a level greater than expected.

Therapeutic drug levels often may be achieved more rapidly when a drug is administered intravenously compared to oral or rectal administration, offering the potential advantage of a more rapid onset of action. This may be particularly desirable in patients with high fever, or in whom fever is causing undesirable symptoms or complications such as febrile seizures. It may also be more convenient to administer medications in an intravenous dosage form, particularly for patients who currently have an intravenous line in place. While Caldolor (intravenous ibuprofen) is approved for the treatment of fever in adults, it has not been approved for the treatment of fever in children. We believe that the availability of Ofirmev in the U.S. would offer a significant new treatment option for hospitalized patients with fever and address unmet medical needs, particularly with respect to the management of fever in children and infants, including premature newborns.

Multi-Modal Pain Management

Multimodal analgesia is the use of two or more analgesic agents that act by different mechanisms to provide superior analgesic efficacy with equivalent or reduced adverse effects. The Practice Guidelines for Acute Pain Management in the Peri-operative Setting from the American Society of Anesthesiologists, or ASA, recommend that multi-modal pain management therapy should be employed whenever possible. The ASA guidelines recommend that all surgical patients receive an around-the-clock regimen of acetaminophen, NSAIDs, or COX-2 inhibitors, and that dosing regimens should be administered to optimize efficacy while minimizing the risk of adverse events. The only intravenous NSAIDs approved in the U.S., Caldolor (ibuprofen), Toradol (ketorolac tromethamine), and generic ketorolac, all carry a boxed warning for the risk of bleeding, renal dysfunction, and other adverse effects.

The concept of using acetaminophen for multi-modal management of pain to improve pain relief and reduce opioid consumption is not new to physicians. In fact, oral acetaminophen-opioid combination products are very commonly prescribed for the treatment of acute pain, including post-operative pain. Such products include Vicodin (hydrocodone plus acetaminophen), Percocet (oxycodone plus acetaminophen), Tylenol Codeine #3 McNeil (codeine plus acetaminophen), Ultram (tramadol plus acetaminophen), and Darvocet (propoxyphene plus acetaminophen). Approximately 73% of the 14.4 billion doses of oral opioids sold in the U.S. in 2008 were combination products that included acetaminophen. Since an intravenous formulation of acetaminophen has not been available in the U.S., physicians have not been able to extend this common multi-modal approach to the peri-operative setting, when patients are unable to take oral medications.

Sales Performance of Intravenous Acetaminophen in Europe

Intravenous acetaminophen is marketed by BMS outside of the U.S. and Canada under the brand name Perfalgan. This product is currently approved in approximately 80 countries and is marketed throughout Europe and other parts of the world. Intravenous acetaminophen was launched on a country-by-country basis, beginning in France in 2002, followed by Germany and Spain in 2003, and Italy and the United Kingdom in 2004. Based on 2008 data from IMS Health, Inc., or IMS, an independent marketing research firm, we estimate that more than 400 million doses of intravenous acetaminophen have been distributed since the introduction of this product in Europe, and it has become the market and unit share leader among injectable analgesics, with approximately 90 million units sold, or approximately $250 million in product sales, in 2008. This performance corresponds to an estimated market share in Europe in 2008 of 20% of all injectable analgesic units, and an estimated 45% market share of all injectable analgesic dollar sales. In some European Union, or E.U., countries, such as France and Belgium, intravenous acetaminophen has a unit market share greater than 40% based on 2008 data from IMS. We believe these and other countries are utilizing intravenous acetaminophen as the foundation for multi-modal analgesia, particularly in the post-operative setting.

U.S. Market Opportunity

We believe that the U.S. market represents a potentially larger sales opportunity for intravenous acetaminophen than Europe with respect to potential unit market share and pricing. We estimate that the U.S. market is comparable to the European market when viewed from the perspective of the number of days of analgesic therapy administered to patients annually, which is calculated based on analgesic equivalent doses of the various therapeutic options. Based on sales reported to IMS in 2008, we have estimated that analgesic equivalent doses represented approximately 90 million analgesic patient days in the E.U., compared to approximately 80 million patient days in the U.S. The E.U. analgesic therapy market consists of intravenous opioids, NSAIDs and acetaminophen. There are multiple intravenous NSAIDs available in Europe, as well as other intravenous opioids not available in the U.S. According to IMS, 287 million vials of injectable analgesics were sold in the U.S. in 2009. Morphine is the current market leader and accounted for more than 159 million vials sold in 2009. Approximately 90 million vials of other injectable opioids, such as meperidine, hydromorphone and fentanyl, which are all available in generic forms, were sold in 2009. Toradol (ketorolac tromethamine), an NSAID that is available as a generic drug, and Caldolor (ibuprofen), another NSAID, are the only non-opioid intravenous injectable analgesics available for treating acute pain in adults in the U.S. According to IMS, more than 38 million vials of injectable ketorolac were sold in the U.S. in 2009.

On average, pharmaceutical pricing continues to be higher in the U.S. than in Europe. According to IMS, the average selling price in Europe in 2008 was approximately $2.85 (U.S. dollars) per vial of Perfalgan, or intravenous acetaminophen. We believe the unit price of Perfalgan in major European countries was largely driven by government-controlled reference pricing in those markets. In Scandinavian countries with less restrictive pricing controls, the average Perfalgan selling price is as high as $10.42 (U.S. dollars) per vial. The price of ketorolac in the U.S. in 1997, prior to the entry of generic competitors, was approximately $7.00 (U.S. dollars) per vial, according to the American Journal of Health-System Pharmacy. The price of Caldolor in the U.S. was $10.50 (U.S. dollars) per 800 mg vial at launch in 2009.

We believe that, upon the approval of Ofirmev in the U.S., the key product attributes that will drive the adoption of this product candidate include the efficacy and safety profile of Ofirmev demonstrated in multiple clinical studies, the excellent safety profile and familiarity physicians have with oral acetaminophen, alone and in combination with opioids, the potential for reducing concomitant use of morphine and other opioids, the need for a more convenient dosage form for patients unable to take mediation orally, and a more rapid onset of action. In a market survey by IMS commissioned by us in 2007, 81% of the 126 U.S. physicians surveyed indicated readiness to use Ofirmev immediately following the product's approval by the FDA.

Clinical Development

Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. Supportive information may also include scientific literature and publicly available information contained in the labeling of other medications. Accordingly, the NDA we submitted for Ofirmev in May 2009 included data from our own clinical trials in the U.S., trials of Ofirmev previously completed by BMS in the U.S. and Europe, and other studies published in the scientific and medical literature. A total of 1,020 adult patients and 355 pediatric patients, consisting of 47 neonates, 64 infants, 171 children and 73 adolescents, received Ofirmev in clinical trials.

New Drug Application (NDA)

We submitted an NDA for Ofirmev to the FDA in May 2009. The NDA was accepted for filing in July 2009, and designated for priority review. In February 2010, we received a complete response letter from the FDA, which stated that the NDA could not be approved in its present form due to deficiencies observed during an inspection of the facilities of our third party manufacturer for this product candidate, which was completed on

February 5, 2010. Our third party manufacturer submitted a response to the FDA on February 18, 2010, and we intend to re-submit a 505(b)(2) NDA for Ofirmev as soon as possible following the resolution of the inspectional observations. The re-submitted NDA will incorporate by reference all of the data in the original NDA and contain updated safety information derived from the use of this product candidate in European and other countries, along with an indication that the deficiencies with respect to good manufacturing practices have been resolved by our third party manufacturer.

We believe that, prior to the receipt of the complete response letter in February 2010, we had substantially completed labeling discussions with the FDA for Ofirmev. Based upon these discussions, we plan to seek approval for the use of Ofirmev for the management of pain and reduction of fever in adults and children. In the complete response letter, the FDA did not indicate that any additional clinical trials were required in order to approve the NDA for Ofirmev and did not cite any safety or efficacy deficiencies. As a result, the following table summarizes the pivotal clinical trial data that will be included in the NDA that we plan to re-submit for Ofirmev:

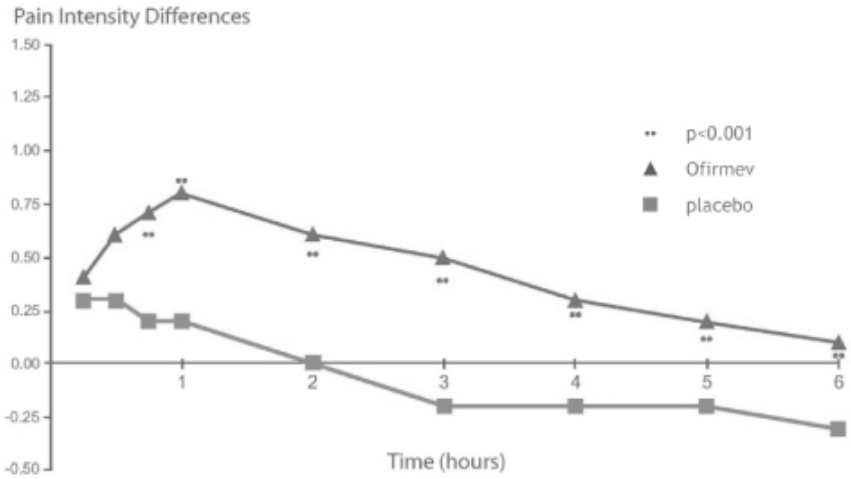
Study	Number of Patients	Trial Design	Trial Outcome
Adult Pain			
Pain Study 1: RC 210 3 002 / Sinatra Study (BMS)	101	Total hip or knee replacement	Intravenous acetaminophen statistically superior to placebo for reduction in pain intensity over 24 hours. Median time to use of rescue medication 3 hours with intravenous acetaminophen compared to 0.8 hours with placebo. Greater reduction in mean morphine consumption through 24 hours with intravenous acetaminophen compared to placebo (38 mg and 57 mg, respectively).
Pain Study 2: Cadence Study 304	244	Abdominal laparoscopic surgery	Intravenous acetaminophen demonstrated statistically significant greater reduction in pain intensity over 24 hours compared to placebo.
Adult Fever			
Fever Study 1: Cadence Study 302	60	Endotoxin-induced fever	Intravenous acetaminophen demonstrated statistically significant antipyretic effect through 6 hours in comparison to placebo.

Pivotal Clinical Trials Supporting Efficacy of Ofirmev in Adult Patients

The pivotal clinical trials supporting the efficacy of Ofirmev for the management of pain and reduction of fever are as follows:

- *Pain Study 1: RC 210 3 002, a Phase III clinical trial in adults with moderate-to-severe pain following total hip or knee replacement surgery*. This trial was a randomized, placebo-controlled, double-blind,

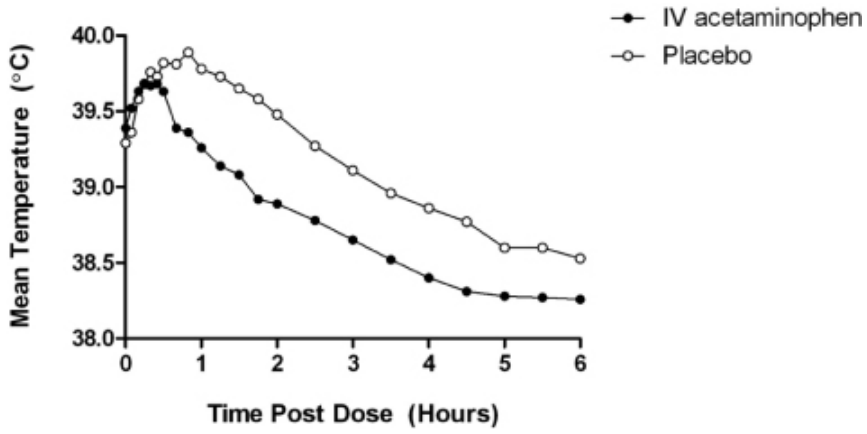
multi-center Phase III study to assess the efficacy and safety of multiple doses of intravenous acetaminophen versus intravenous propacetamol or placebo. The primary efficacy endpoint of time-specific pain relief scores from 15 minutes to six hours was statistically significant ($p<0.05$) in favor of Intravenous acetaminophen compared to placebo at all time points. Key secondary endpoints of time-specific pain intensity differences through six hours, weighted sum of pain intensity differences over six hours, weighted sum of pain relief differences over six hours, time to administration of the first rescue medication, patient global evaluation at 24 hours, and rescue medication consumption over 24 hours, were all statistically significant ($p<0.05$) in favor of Intravenous acetaminophen compared to placebo. There was a 33% reduction in the amount of opioid used as rescue medication in the group treated with Intravenous acetaminophen, and yet they reported a superior pain experience, as indicated by the global satisfaction rating. In addition to the results originally reported, we have performed a re-analysis of the data from this trial using endpoints that the FDA currently favors for acute pain studies. Based upon our re-analysis of the sum of pain intensity differences over 24 hours, or SPID24, Intravenous acetaminophen was shown to be superior to placebo ($p<0.0001$). The following graph presents the pain intensity differences from the baseline measurements reported by patients in this study at each time point from 15 minutes to six hours:



Study RC 210 3 002 also demonstrated a statistically significant improvement in patient satisfaction with pain treatment for patients who received intravenous acetaminophen compared to placebo. The study results indicate that nearly twice as many subjects noted good or excellent results at 24 hours compared to placebo. The number of drug-related adverse events reported for the group of patients who received intravenous acetaminophen in this trial was similar to the number of events reported for the placebo group. The table below provides a summary of these data from the trial:

	Intravenous acetaminophen	Intravenous placebo	p-value
Sum of pain intensity differences over 24 hours	0.4	-235	<0.0001
Weighted sums of pain relief over six hours	6.6	2.2	<0.05
Good/excellent global evaluation at 24 hours	41%	23%	<0.01
Rescue medication (morphine) consumption over 24 hours (mg)	38.3 (33% decrease)	57.4	<0.001
Safety	Intravenous acetaminophen was comparable to placebo		

- *Pain Study 2: Cadence Study 304, a Phase III clinical trial in adult patients with moderate to severe pain following abdominal laparoscopic surgery*. This trial was a randomized, placebo-controlled, double-blind, multi-center study of 244 patients to assess the efficacy and safety of two dosing regimens of Ofirmev, 1000 mg administered every six hours and 650 mg administered every four hours, compared to placebo over a 24-hour period. In December 2008, we announced that this study successfully met its primary endpoint of a statistically significant reduction in summed pain intensity differences from baseline over 24 hours, or SPID24, for Ofirmev1000 mg compared to placebo ($p < 0.01$). The trial also achieved a statistically significant reduction in SPID24 for the 650 mg dose administered every four hours ($p = 0.02$). Consistent with other placebo-controlled clinical trials with Ofirmev, the number of safety events reported for the group of patients who received Ofirmev was similar to the number of safety events reported for the placebo treatment group.
- *Fever Study 1: Cadence Study 302, a Phase III clinical trial in adults with fever*. The efficacy of Ofirmev1000 mg in the treatment of adult fever was evaluated in one randomized, double-blind, placebo- controlled clinical trial. The study was a 6-hour, single-dose, endotoxin-induced fever study in 60 healthy adult males. A statistically significant antipyretic effect of Ofirmev was demonstrated through 6 hours in comparison to placebo. The mean temperature over time is shown below:



Clinical Trials Supporting Safety and Pharmacokinetics in Adult Patients

A total of 1,020 adult patients have received Ofirmev in clinical trials, including 380 patients (37.3%) who received five or more doses, and 173 patients (17.0%) who received more than ten doses. Most patients were treated with 1,000 mg of Ofirmev every six hours. A total of 134 patients (13.1%) received 650 mg of Ofirmev every four hours. The most common adverse events in adult patients treated with Ofirmev (incidence ³ 5% and greater than placebo) were nausea, vomiting, headache, and insomnia.

The safety of acetaminophen has been well-established through decades of use in oral and suppository formulations. The primary safety concern with acetaminophen is hepatotoxicity, which is a well-understood and dose-dependent effect. Liver failure can occur in people who have taken a substantial overdose of acetaminophen, but it occurs only rarely when acetaminophen is dosed in accordance with the recommended guidelines. In addition, an effective antidote, N-acetylcysteine, is available to treat acetaminophen overdose.

In pharmacokinetic trials, the average peak plasma concentration of acetaminophen was briefly higher for Ofirmev when compared to the same dose of oral acetaminophen, but levels over time were not meaningfully different. These trials also demonstrated that Ofirmev does not accumulate over multiple doses after 12 hours and that urinary elimination of acetaminophen metabolites, including metabolites with potential to interact with the liver, was not meaningfully different for Ofirmev compared to oral acetaminophen at 12 and 24 hour measurements.

In addition to the pivotal clinical trials described above, data from the following clinical trials will be included in our re-submitted NDA to support the safety and the pharmacokinetic profile of Ofirmev in adults:

- *Cadence Study 301, a Phase III clinical trial in adult patients with moderate-to-severe pain following gynecologic surgery*. This clinical trial was a randomized, placebo-controlled, double-blind, multi-center study to assess the safety and efficacy in adult, female patients of single and multiple doses of Ofirmev versus placebo over a 48-hour period. While this study conducted in 331 patients did not meet its primary efficacy endpoint, the number of adverse events in the group of patients that received Ofirmev was comparable to the group of patients in the placebo arm. There were no clinically relevant differences in adverse event reports over the 48-hour study period, and at the follow-up on day seven, between Ofirmev and placebo patients in the frequency of serious, severe, related, hepatic or overall adverse events. There was no evidence of local venous irritation or infusion-related pain with Ofirmev. The frequency of quantitative liver enzyme elevations (alanine aminotransferase or aspartate aminotransferase), while comparable between the treatment groups, was more than twice as high in the placebo group as compared to the Ofirmev group.
- *Cadence Study 303, a Phase III clinical trial in adults with experimentally-induced fever versus oral acetaminophen*. This trial was a single-dose, endotoxin-induced fever study conducted in 81 healthy adult males. Ofirmev was more efficacious than oral acetaminophen in rapidly blunting and reducing endotoxin-induced fever within 2 hours after administration (WSTD2, p=0.0039). Ofirmev demonstrated a more rapid onset of action compared to oral acetaminophen at 30 minutes (p=0.0202).
- *Cadence Study 351, a Phase III safety study in adult patients*. This clinical trial, which was designed to evaluate the safety of repeated doses of Ofirmev in adults for up to five days, was an open-label, multi-center study of 213 hospitalized patients randomized to receive repeated doses of Ofirmev 1,000 mg every six hours, Ofirmev 650 mg every four hours, or standard of care treatment. In this trial, the hepatic and general safety profile of the group of patients that received Ofirmev was comparable to the standard of care treatment group, with numerically lower proportions of patients with elevated liver function tests in the two Ofirmev groups compared to the standard of care treatment group.
- *Cadence Study 101, a pharmacokinetic study in adults*. This clinical trial was a randomized, single-center study to assess the pharmacokinetics in adults of single and multiple doses of Ofirmev compared to oral acetaminophen. The results of this trial demonstrated that Ofirmev produced a mean first dose maximum plasma concentration that was briefly up to approximately 75% higher than oral acetaminophen. However, overall drug exposure, which is also known as the area under the curve, was essentially the same for Ofirmev and oral acetaminophen. The maximum plasma concentration for Ofirmev occurred at the end of the 15 minute infusion and occurred 30 minutes earlier than the observed maximum value for oral acetaminophen. The elimination half-life and volume of distribution values were comparable and not significantly different across treatment groups. Oral acetaminophen was 94% bioavailable in this study, indicating there should not be a need for physicians to convert their preferred dosage amounts when they switch between Ofirmev and oral acetaminophen. Steady state levels of acetaminophen were achieved rapidly, as no drug accumulation occurred from 12 to 48 hours with repeated dosing. As expected, neither Ofirmev nor oral acetaminophen had a significant effect on platelet aggregation. There were no significant differences observed between the intravenous and oral acetaminophen groups with respect to the number of adverse events, including adverse hepatic events.

Clinical Trials Supporting Safety and Efficacy in Pediatric Patients

A total of 355 pediatric patients, consisting of 47 neonates, 64 infants, 171 children, and 73 adolescents, have received Ofirmev, including 212 patients (59.7%) who received five or more doses and 153 (43.1%) who received more than ten doses. Pediatric patients received Ofirmev doses up to 15 mg of Ofirmev per kg of body weight every four, six or eight hours. The maximum exposure was 7.7 days in neonates, 6.4 days in infants, 6.8 days in children and 7.1 days in adolescents. The most common adverse events (incidence ³ 5%) in pediatric patients treated with Ofirmev were nausea, vomiting, constipation, pruritus, agitation, and atelectasis.

Data from the following clinical trials will be included in our NDA for Ofirmev to demonstrate comparable pharmacokinetics between children and adults:

- *Cadence Study 102, a pharmacokinetic study in pediatric patients*. This clinical trial, which was designed to evaluate the pharmacokinetics of single and multiple doses of Ofirmev in 75 pediatric patients, demonstrated a pharmacokinetic profile for Ofirmev generally comparable to adults, with an age-related reduction in clearance in newborns. Ofirmev was well-tolerated across all age groups, ranging from newborns to adolescents.
- *Cadence Study 352, a safety study in pediatric patients*. This clinical trial was an open-label, multi-center, multi-day study to assess the safety in children of repeated doses of up to 15 mg of Ofirmev per kg of body weight over at least five days**.** One neonate, eight infants and 91 children and adolescents requiring analgesic or antipyretic therapy were included in this study. Ofirmev was administered at a dose of 30 to 50 mg per kg of body weight per day every six or eight hours for neonates and 40 to 75 mg per kg of body weight per day every four or six hours for older pediatric patients, for periods of up to seven days. Ofirmev was well tolerated in this relatively sick and complicated pediatric inpatient population. There were no clinically relevant differences between the treatment groups in the frequency of serious, severe, or overall treatment-emergent adverse effects. The majority of treatment-emergent adverse effects was deemed unrelated to Ofirmev and nearly all cases were mild or moderate in severity. A small number of patients experienced hepatic treatment-emergent adverse effects which may have been related to the treatment, or which could have resulted from a reporting bias inherent in the open-label design of the clinical trial, and the possibility that clinical study staff may have been hypervigilant in checking for liver function test elevations.

Published Clinical Trial Data Supporting Efficacy and Safety

We plan to also reference the following non-pivotal clinical trials from published medical literature in our re-submitted NDA for Ofirmev:

- *Cattabriga, et al., a clinical trial in adults following cardiac surgery*. This clinical trial evaluated the analgesic efficacy of repeated 1,000 mg doses of intravenous acetaminophen given every six hours over 72 hours as part of an adjunctive, multimodal treatment program with intravenous tramadol given to 113 patients as a continuous infusion to treat pain after open-heart surgery. At 12, 18, and 24 hours after the end of the surgery, patients who received intravenous acetaminophen plus tramadol had significantly less pain at rest than those who received placebo plus tramadol ($p=0.0041$, $p=0.0039$, and $p=0.0044$, respectively). The group of patients who received intravenous acetaminophen also required less cumulative morphine than the placebo group (48 mg versus 97 mg).
- *Atef, et al., a clinical trial in adults following elective tonsillectomy*. This clinical trial evaluated the analgesic efficacy of repeated doses of intravenous acetaminophen in 76 adult patients undergoing tonsillectomy. Intravenous acetaminophen was significantly better than placebo on average pain at rest and on swallowing ($p<0.001$), and the frequency of insufficient pain relief, which was defined as a visual analog scale, or VAS, score of >30 mm at rest and >50 mm on swallowing ($p<0.001$). Significantly more patients in the intravenous acetaminophen group did not require any rescue opioid medication (71%) compared with the placebo group (0%), and total average consumption of the opioid meperedine over 24 hours was reduced by 77% ($p<0.001$).

Post-Approval Commitments

As part of the approval process for Ofirmev, the FDA issued a formal written request under Section 505A of the U.S. Food, Drug and Cosmetic Act, requiring us to perform an additional pediatric clinical trial as a post-approval commitment. Following the approval of an NDA for Ofirmev, we plan to complete this pediatric clinical trial and, upon the acceptance by the FDA of the data from this study, we will be eligible for an additional six months of marketing exclusivity for Ofirmev. To date, the FDA has not communicated any other post-approval commitments to us.

Commercialization Strategy

We are preparing to build a commercial organization in the U.S. focused on promoting Ofirmev to physicians, nurses and pharmacists principally in the hospital setting. We believe that we can achieve our strategic goals by deploying an experienced sales organization supported by an internal marketing infrastructure that targets institutions with the greatest use of pharmaceutical products. We will consider opportunities to partner Ofirmev, along with any other product candidates we may acquire in the future, to reach markets outside the U.S. or to expand our reach to other physician groups outside the hospital, where applicable.

The U.S. Hospital Market

Large, multinational pharmaceutical companies have generally decreased marketing efforts focused on hospital-use drugs, instead focusing on drugs that can be marketed in the larger outpatient setting. We believe this reduced emphasis on the hospital marketplace presents us with an excellent opportunity to market products that address unmet medical needs in the hospital setting. We believe the concentrated nature of the hospital marketplace will allow for our expansion into other therapeutic areas without substantial investment in additional commercial infrastructure.

According to IMS, in 2004 approximately $28 billion was spent on promotional activities by the pharmaceutical industry in the U.S. Of this amount, IMS estimates that only $1 billion was directed towards hospital-based physicians and directors of pharmacies. This hospital-focused spending represents approximately 3% of total promotional expenditures and has declined from approximately 6% of total spending in 1996. The significant imbalance towards the outpatient market is highlighted by spending on direct-to-consumer campaigns and drug sampling which now make up close to 80% of promotional spending for pharmaceuticals.

Despite these declining promotional expenditures, U.S. hospitals and clinics accounted for approximately $54 billion or 21% of U.S. pharmaceutical sales in 2005, according to IMS. Furthermore, we believe pharmaceutical sales to acute care hospitals are highly concentrated among a relatively small number of large institutions. For example, according to Wolters Kluwer Health, an independent marketing research firm, 1,800 of the approximately 5,000 acute care hospitals in the U.S. represent approximately 80% of hospital injectable analgesic sales. The concentration of high-prescribing institutions enables effective promotion of pharmaceuticals utilizing a relatively small, dedicated sales and marketing organization. We believe the relative lack of promotional efforts directed toward the highly concentrated hospital marketplace makes it an underserved and compelling opportunity, especially for a biopharmaceutical company commercializing its products directly through its own dedicated sales force.

We believe a typical sales representative focused on office-based physicians can generally promote only two to three products effectively; whereas, a typical hospital-focused sales representative can effectively promote five to six products. Furthermore, we believe a typical sales representative focused on office-based physicians can effectively reach five to seven physicians per day; whereas, a typical hospital-focused sales representative can reach many more physicians, nurses and pharmacy directors within a given institution. Notably, a hospital-focused sales representative also faces significantly less travel time between sales calls and less wait time in physician offices as a large number of prescribers can be found in a single location. Furthermore, drug sampling generally does not occur in hospitals, which represents a significant cost advantage versus marketing to office-based physicians. A single sales representative can promote products from multiple therapeutic categories to multiple prescribers within the institution.

Sales and Marketing

We are building a commercial organization in anticipation of the approval and launch of Ofirmev. To date, we have hired an experienced commercial management, marketing and sales operations team, and plan to hire a field sales force of approximately 150 fully-dedicated hospital sales specialists following approval of our NDA for Ofirmev.

The primary target audience for Ofirmev will include anesthesiologists and surgeons. Other targets will include certified registered nurse anesthetists, emergency medicine physicians, intensivists, internists, obstetricians and other physicians throughout the hospital. Our commercial sales force will focus on reaching the top 1,800 U.S. hospitals, which we believe represent approximately 80% of the market opportunity for Ofirmev.

We believe that our sales force will be differentiated by its level of experience and background in the industry. Our sales management team has an average of 16 years of pharmaceutical industry experience, and an average of seven years of hospital sales management experience. We will require that our sales representatives complete a comprehensive training program focused on our product, therapeutic area, competitive products, sales techniques and compliance with applicable laws and regulations. This training program will include field-based learning to provide our representatives with a comprehensive understanding and perspective on the unmet medical needs in the management of pain and fever in adults and children and how Ofirmev, if approved, may address those needs.

Field-based regional business directors and district sales managers will provide oversight for our hospital sales specialists and direct our efforts to provide hospital customers with the information needed to obtain Ofirmev formulary adoption and utilization. Because our clinical studies of Ofirmev have been conducted across a wide range of surgical procedures, we believe that providing access to this data and the unique characteristics of Ofirmev will assist physicians in using Ofirmev safely and effectively. In addition to our hospital sales specialists, we will also implement a variety of marketing programs to educate customers, including direct-to-physician promotional materials, peer-to-peer educational programs, medical journal advertising, and participation in targeted medical convention programs.

Licensing Agreements

In March 2006, we in-licensed from BMS the patents and the exclusive development and commercialization rights to Ofirmev in the U.S. and Canada. BMS has sublicensed these rights to us under a license agreement with SCR Pharmatop S.A., or Pharmatop.

As consideration for the license, we paid a $25.0 million up-front fee and will be required to pay a $15.0 million fee within ten business days after approval of the product. In addition to the payment upon approval, we may be required to make future milestone payments totaling up to $25.0 million upon the achievement of various milestones related achievement of certain net sales levels of Ofirmev. We are also obligated to pay a royalty on net sales of the product. We have the right to grant sublicenses to our affiliates.

The term of the Ofirmev agreement generally extends on a country-by-country basis until the last licensed patent expires, which is expected to occur in 2022. Either party may terminate the Ofirmev agreement upon delivery of written notice if the other party commits a material breach of its obligations and fails to remedy the breach within a specified period or upon the occurrence of specified bankruptcy, reorganization, liquidation or receivership proceedings. In addition, BMS may terminate the Ofirmev agreement if we breach, in our capacity as a sublicensee, any provision of the agreement between BMS and Pharmatop. The Ofirmev agreement will automatically terminate in the event of a termination of the license agreement between BMS and Pharmatop. We may terminate the Ofirmev agreement at any time upon specified written notice to BMS after the occurrence of events of default that relate to our territory and would entitle BMS to terminate the Pharmatop license agreement. The events of default include Pharmatop’s inability to maintain specified claims under listed patents, the marketing by a third party of a parenterally-administered product containing acetaminophen, subject to certain conditions, or a successful third party action that deprives Pharmatop of its rights to specified patents. We may also terminate the Ofirmev agreement upon specified written notice after an uncured failure by Pharmatop to perform any of its material obligations under the Pharmatop license agreement with respect to our territory that would permit BMS to terminate the Pharmatop license agreement.

Either BMS or Pharmatop may terminate the license agreement between them upon delivery of written notice after an uncured failure by the other party to perform any of its material obligations under the license agreement. BMS may generally terminate the agreement upon written notice to Pharmatop within a specified period so long as all payments due under the agreement to Pharmatop are current. Pharmatop may terminate the agreement upon specified written notice if BMS opposes any of the listed patent applications or challenges the validity or enforceability of any of the listed licensed patents. BMS is also entitled to terminate the Pharmatop agreement upon the occurrence of events of default that relate to the territory described above.

Intellectual Property

We are the exclusive licensee of two U.S. patents and two pending Canadian patent applications from Pharmatop, under BMS's license to these patents from Pharmatop. U.S. Patent No. 6,028,222 (Canadian patent application 2,233,924) covers the formulation of Ofirmev and expires in August 2017. U.S. Patent No. 6,992,218 (Canadian patent application 2,415,403) covers the process used to manufacture Ofirmev and expires in June 2021.

Manufacturing and Distribution

In July 2007, we entered into a development and supply agreement with Baxter Healthcare Corporation, or Baxter, for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of Ofirmev. Pursuant to the terms of the agreement with Baxter, Baxter will receive development fees from us upon the completion of specified development activities, which we are expensing as incurred. In addition, Baxter will receive a set manufacturing fee based on the amount of the finished Ofirmev drug product produced, which prices may be adjusted by Baxter, subject to specified limitations. We are also obligated to purchase a minimum number of units each year throughout the five-year term of the agreement, or pay Baxter an amount equal to the per-unit purchase price multiplied by the amount of the shortfall. Further, we are obligated to reimburse Baxter for all reasonable costs directly related to work performed by Baxter in support of any change in the active pharmaceutical ingredient, or API, source or API manufacturing process.

On February 10, 2010, we received a complete response letter from the FDA, which stated that the NDA could not be approved in its present form due to deficiencies with respect to good manufacturing practices observed during the agency's inspection of Baxter's facilities used to manufacture Ofirmev, which was completed on February 5, 2010. In the complete response letter, the FDA did not indicate that any additional clinical trials were required in order to approve the NDA for Ofirmev and did not cite any safety or efficacy deficiencies. On February 18, 2010, Baxter submitted a response letter concerning the good manufacturing practice observations to the FDA. As soon as the inspectional observations are resolved, we plan to re-submit the NDA for Ofirmev.

We plan to distribute Ofirmev primarily to drug wholesalers, who in turn will distribute the product to hospital pharmacies and other institutional customers. We have retained third-party service providers to perform a variety of functions related to the distribution of Ofirmev, including warehousing, customer service, order-taking, invoicing, collections, shipment and returns processing. We are also planning to enter into agreements with wholesalers, under which we will receive certain distribution management services and data reporting in exchange for a fee.

Competition

The pharmaceutical industry is subject to intense competition and characterized by extensive research efforts and rapid technological progress. Competition in our industry occurs on a variety of fronts, including developing and bringing new products to market before others, developing new technologies to improve existing products, developing new products to provide the same benefits as existing products at lower cost and developing new products to provide benefits superior to those of existing products. There are many companies, including

generic manufacturers as well as large pharmaceutical companies, that have significantly greater financial and other resources than we do, as well as academic and other research institutions that are engaged in research and development efforts for the indications targeted by our product.

A variety of competitive products from two main drug classes, opioids and NSAIDs, are currently available in the market for treatment of pain and fever in hospitalized patients, including:

Injectable opioids

- morphine, the leading product for the treatment of acute post-operative pain, a generic version of which is available from several manufacturers;
- DepoDur, an extended release injectable (epidural) formulation of morphine; and
- other injectable opioids, including fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers.

Injectable NSAIDs

- Toradol (ketorolac tromethamine), an injectable NSAID, a generic version of which is available from several manufacturers; and
- Caldolor (ibuprofen), another injectable NSAID.

Product Candidates

We are also aware of a number of product candidates in development to treat acute pain, including injectable NSAIDs, novel opioids, new formulations of currently available opioids, long-acting local anesthetics and new chemical entities as well as alternative delivery forms of various opioids, COX2 inhibitors, and NSAIDs. A variety of pharmaceutical and biotechnology companies are developing these new product candidates, including but not limited to Acusphere, Inc., Anesiva, Inc., Cara Therapeutics, Inc., Cephalon, Inc., Durect Corporation, Javelin Pharmaceuticals, Inc., NeurogesX, Inc., Pacira Pharmaceuticals, Inc., Paion AG, St. Charles Pharmaceuticals, Inc., and TheraQuest Biosciences, LLC.

Government Regulation

Governmental authorities in the U.S. and other countries extensively regulate the testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution, among other things, of pharmaceutical products. In the U.S., the FDA, under the Federal Food, Drug and Cosmetic Act and other federal statutes and regulations, subjects pharmaceutical products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

We and our manufacturers and clinical research organizations may also be subject to regulations under other federal, state and local laws, including the Occupational Safety and Health Act, the Environmental Protection Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations, of other countries.

FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product and proposed labeling. The testing and collection of data and the preparation of necessary applications are

expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

The process required by the FDA before a new drug may be marketed in the U.S. generally involves the following: completion of preclinical laboratory and animal testing in compliance with FDA regulations, submission of an investigational new drug application, or IND, which must become effective before human clinical trials may begin, performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use, and submission and approval of an NDA by the FDA. The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap. In Phase I clinical trials, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more dosages. In Phase II clinical trials, in addition to safety, the sponsor evaluates the efficacy of the product on targeted indications, and identifies possible adverse effects and safety risks in a patient population. Phase III clinical trials typically involve testing for safety and clinical efficacy in an expanded population at geographically-dispersed test sites.

Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at each clinical site and may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

The applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the policies agreed to by the FDA under PDUFA, the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA's evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA and issue a complete response letter.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for new indications or improved formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Amendments permit the applicant to rely upon the FDA's findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or some of the label indications for which the referenced product has been approved, or the new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product. A certification that the new product will not infringe the already approved product's Orange Book-listed patents or that such patents are invalid is called a paragraph IV certification. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA and patent holders once the NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. For drugs with five-year exclusivity, if an action for patent infringement is initiated after year four of that exclusivity period, then the 30-month stay period is extended by such amount of time so that 7.5 years has elapsed since the approval of the NDA with five-year exclusivity. This period could be extended by six months if the NDA sponsor obtains pediatric exclusivity. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2) and one pharmaceutical company has sued the FDA on the matter. Although the issues in that litigation are specific to the products involved, if the FDA does not prevail, it may be required to change its interpretation of Section 505(b)(2), which could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

Fast Track Designation

A drug designated as a fast track product by the FDA must be intended for the treatment of a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation does not apply to a product alone, but applies to a combination of the product and specific indication for which it is being studied. A sponsor may submit a request for fast track designation at the time of original submission of its IND, or at any time thereafter prior to receiving marketing approval of its NDA. Fast track status enables the sponsor to have more frequent and timely communication and meetings with the FDA regarding the product development plans. Fast track status may also result in eligibility for NDA priority review, under which the PDUFA review goal for the NDA is six months rather than ten months.

The Hatch-Waxman Act

Under the Hatch-Waxman Act, newly-approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. Hatch-Waxman prohibits the submission of an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA for another version of such drug

during the five-year exclusive period; however, as explained above, submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under Hatch-Waxman will not prevent the submission or approval of another full NDA; however, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. Additionally, six months of marketing exclusivity is available under Section 505A of the FDCA if, in response to a written request from the FDA, a sponsor submits and the agency accepts certain requested information relating to the use of the approved drug in the pediatric population.

Other Regulatory Requirements

We may also be subject to a number of post-approval regulatory requirements. If we seek to make certain changes to an approved product, such as promoting or labeling a product for a new indication, making certain manufacturing changes or product enhancements or adding labeling claims, we will need FDA review and approval before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications or product enhancements and, in some cases, for manufacturing and labeling claims, is generally a time-consuming and expensive process that may require us to conduct clinical trials under the FDA's IND regulations. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. In addition, it has been reported that the new presidential administration may be seeking to curb practices that could result in the extension of the term of patent protection for pharmaceuticals, which may include applications for new indications or product enhancements.

Adverse experiences associated with use of the products must be reported to the FDA, and FDA rules govern how we can label, advertise or otherwise commercialize our products. There are current post-marketing safety surveillance requirements that we will need to meet to continue to market an approved product. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal health care programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition,

certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we and the manufacturers on which we rely for the manufacture of our products are subject to requirements that drugs be manufactured, packaged and labeled in conformity with current good manufacturing practice. To comply with current good manufacturing practice requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, record-keeping and other requirements. The FDA periodically inspects drug manufacturing facilities to evaluate compliance with current good manufacturing practice requirements.

Also, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning record-keeping and control procedures.

Outside of the U.S., our ability to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process includes all of the risks associated with the FDA approval process described above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country.

Third-Party Reimbursement and Pricing Controls

In the U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of coverage and reimbursement to providers and the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

In many foreign markets, including Canada, pricing of pharmaceutical products is subject to governmental control. In the U.S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

Employees

As of February 1, 2010, we had 90 employees. A total of 31 employees were engaged in clinical research, regulatory, quality assurance and product and manufacturing development, 40 employees were in sales, marketing, commercial operations, medical affairs and business development and 19 employees were in administration and finance.

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

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations.

Risks Related to Our Business and Industry

We currently have no drug products for sale, and only one drug product candidate, Ofirmev™. We are dependent on the success of Ofirmev™, and cannot guarantee that this product candidate will receive regulatory approval or be successfully commercialized.

Our business success depends on our ability to obtain regulatory approval for and successfully commercialize our only product candidate, Ofirmev, and any significant delays in obtaining approval for and commercializing Ofirmev will have a substantial adverse impact on our business and financial condition.

If approved, our ability to generate revenues from Ofirmev will depend on our ability to:

- hire, train, deploy and support our sales force;
- create market demand for Ofirmev through our own marketing and sales activities, and any other arrangements to promote this product candidate we may later establish;
- obtain sufficient quantities of Ofirmev from our third-party manufacturers as required to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms; and
- maintain patent protection and regulatory exclusivity for Ofirmev.

We may not receive regulatory approval for Ofirmev, or its approval may be further delayed, which would have a material adverse effect on our business and financial condition.

The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources. For example, we submitted a New Drug Application, or NDA, for Ofirmev to the Food and Drug Administration, or FDA, in May, 2009. The NDA was accepted for filing in July 2009, and designated for priority review. Pursuant to Prescription Drug User Fee Act, or PDUFA, guidelines, the FDA was expected to complete its review and provide an action letter with respect to the NDA in November 2009; however, the agency instead indicated that its review would be extended for up to three additional months, resulting in a new PDUFA goal date in February 2010. On February 10, 2010, we received a complete response letter from the FDA, which stated that the NDA could not be approved in its present form due to deficiencies with respect to good manufacturing practices observed during the agency's inspection of the facilities of our third party manufacturer, which was completed on February 5, 2010. On February 18, 2010, our third party manufacturer submitted a response to the FDA, and we intend to re-submit a 505(b)(2) NDA for Ofirmev as soon as possible following the resolution of the inspectional observations. We plan to incorporate by reference all of the data in the original NDA, adding only relevant information regarding the resolution of the deficiencies with respect to good manufacturing practices, and updated safety information derived from the use of this product candidate in European and other countries.

Our plans to re-submit an NDA for Ofirmev will be delayed if the FDA is not satisfied with the response by our third party manufacturer, or if the FDA determines that it must re-inspect the facilities used to manufacture Ofirmev before agreeing that the inspectional observations have been adequately addressed. Additionally, our

planned re-submission of an NDA for Ofirmev will be delayed if the FDA does not agree that the registration batches submitted in our original NDA are fully representative of the manufacturing process and thus meet the requirements for batches that may be used to provide evidence of stability for this product candidate. In such an event, we would be required to include information regarding the stability of other batches of Ofirmev or, potentially, to manufacture new batches in order to provide the necessary stability data prior to re-submitting an NDA, which could delay our planned re-submission and cause us to incur significant additional expenses.

As part of its standard procedures, the FDA will require us to provide updated safety information when we re-submit the NDA for Ofirmev, including safety information derived from the use of this product candidate in European and other countries. Any reports of unanticipated adverse events that are included in this report could influence the FDA's decision as to whether to approve our NDA, or cause the FDA to re-evaluate previously reviewed portions of the NDA and lead to new data requests, which could result in additional delays. Such unanticipated adverse events could also cause the agency to require that we add unfavorable statements, such as warnings or contraindications, to the labeling for Ofirmev, if approved.

Additionally, our NDA for Ofirmev may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval prior to the re-submission of our NDA during the review period. For example, although many products have been approved by the FDA in recent years under Section 505(b)(2) under the Federal Food, Drug and Cosmetic Act, objections have been raised to the FDA's interpretation of Section 505(b)(2). If challenges to the FDA's interpretation of Section 505(b)(2) are successful, the agency may be required to change its interpretation, which could delay or prevent the approval of our NDA for Ofirmev. The review of our re-submitted NDA may also be delayed due to the FDA's internal resource constraints.

Any significant delay in re-submitting an NDA and obtaining FDA approval for Ofirmev, or a second non-approval, could negatively impact our ability to ultimately obtain marketing authorization for this product candidate and would have a material adverse effect on our business and financial condition.

If our contract manufacturer fails to complete pre-commercialization manufacturing development activities for Ofirmev on a timely basis or fails to comply with stringent regulatory requirements, we will face delays in our ability to obtain regulatory approval for, and to commercialize, this product candidate, and our costs will increase.

We do not manufacture Ofirmev, and do not currently plan to develop any capacity to do so. Instead, we have relied on a third-party manufacturer, Baxter Healthcare Corporation, or Baxter, to manufacture and perform important pre-commercialization manufacturing development activities for this product candidate. As part of the process for obtaining regulatory approval, we must demonstrate that the facilities, equipment and processes used to manufacture Ofirmev are capable of consistently producing a product that meets all applicable quality criteria, and that is comparable to the product that was used in our clinical trials. We must also provide the FDA with information regarding the validation of the manufacturing facilities, equipment and processes of our third-party manufacturer, and data supporting the stability of our product candidate. If Baxter is not in compliance with current good manufacturing practice requirements, the approval of our marketing application may be delayed, existing product batches may be compromised, and we may experience delays in the availability of this product candidate for commercial distribution.

For example, on February 10, 2010, we received a complete response letter from the FDA regarding our NDA submission for Ofirmev, which stated that the NDA could not be approved in its present form due to deficiencies observed during an inspection of the facilities used by Baxter to produce this product candidate, which was completed on February 5, 2010. On February 18, 2010, Baxter submitted a response to the FDA. If the FDA is not satisfied with Baxter's response and any corrective actions taken by Baxter, or if the FDA determines that it is necessary to re-inspect Baxter's facilities before agreeing that the inspectional observations have been adequately addressed, we may be required to complete additional manufacturing development activities or provide other information in order to re-submit our NDA, which could cause substantial delays, increase our costs and have a material adverse effect on our business and financial condition.

If Ofirmev is approved and our contract manufacturer fails to produce the product in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of this product candidate or be unable to meet market demand, and may lose potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We have entered into a development and supply agreement with Baxter for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of Ofirmev. Any termination or disruption of our relationships with Baxter may materially harm our business and financial condition, and frustrate any commercialization efforts for this product candidate.

In order to meet anticipated demand for Ofirmev if this product candidate is approved, Baxter has initiated planning activities to install additional production lines, and we have ordered additional, specialized processing equipment to expand the manufacturing capacity for Ofirmev. This processing equipment is currently available from a single source, and if this equipment is not delivered on time or at all, Baxter's ability to increase the manufacturing capacity for Ofirmev to keep pace with anticipated demand will be substantially impacted.

We are currently negotiating a supply agreement for the commercial supply of the active pharmaceutical ingredient, or API, for Ofirmev. If we need to change to another manufacturer or significantly change the manufacturing processes for this product, we may be required to repeat or perform additional pre-clinical or clinical testing, which could increase our costs and cause delays in our ability to obtain regulatory approval for and commercialize the product.

All of our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including current Good Manufacturing Practice requirements enforced by the FDA through its facilities inspection program, and we have little control over their compliance with these regulations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If the commercial manufacturers upon whom we rely to manufacture Ofirmev, and any other product candidates we may in-license, fail to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

The FDA may determine that Ofirmev has undesirable side effects that could delay or prevent its regulatory approval or commercialization.

If concerns are raised regarding the safety of a new drug as a result of undesirable side effects identified during clinical testing, the FDA may decline to approve the drug at the end of the NDA review period or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the drug. The number of such requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by Ofirmev could also result in the inclusion of unfavorable information in our product labeling, denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of this product candidate.

For example, the adverse events observed in the Ofirmev clinical trials completed to date include transient liver enzyme elevations, nausea or vomiting, allergic reactions, and pain or local skin reactions at the injection

site. When used in excess of the current guidelines for administration, acetaminophen has an increased potential to cause liver toxicity. While the rate of adverse events in our clinical trials was comparable between the group of patients who received Ofirmev and those who were in the placebo or control groups and, as a result, we do not expect the administration of acetaminophen in intravenous form will result in an increased risk of toxicity to the liver compared with an equivalent dose of acetaminophen administered orally, we cannot be certain that increased liver toxicity or other drug-related side effects will not be observed in future clinical trials, or as a result of sales of the same formulation of intravenous acetaminophen by BMS in European and other countries, or that the FDA will not require additional trials or impose more severe labeling restrictions due to liver toxicity or other concerns. In June 2009, the FDA convened an advisory panel to make recommendations regarding minimization of the risk of significant liver toxicity due to overdoses with oral acetaminophen, primarily in the outpatient setting. While we do not believe that the panel's specific recommendations will negatively affect Ofirmev, the FDA may take actions different from, or in addition to, those recommended by the panel.

If Ofirmev receives marketing approval and we or others later identify undesirable side effects caused by this product:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of Ofirmev or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

Even if Ofirmev receives regulatory approval, it and any other products we may market will remain subject to substantial regulatory scrutiny.

Ofirmev and any other product candidates we may license or acquire will also be subject to ongoing FDA requirements with respect to the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product, including withdrawal of the product from the market.

If Ofirmev or any other product we may license or acquire fails to comply with applicable regulatory requirements, such as current Good Manufacturing Practices, a regulatory agency may:

- issue warning letters or untitled letters;
- require our contract manufacturer to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose fines other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

In addition to FDA restrictions, numerous other federal, state and local laws and regulations apply to the promotion and sale of pharmaceutical products, such as federal anti-kickback and false claims statutes. For example, the federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, criminal fines and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product’s labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These “off-label” uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

Although the FDA has indicated that our proposed trade name for intravenous acetaminophen, Ofirmev™, is acceptable, the agency may not ultimately approve this trade name.

Ofirmev, or any other trade name that we intend to use for intravenous acetaminophen, must be approved by the FDA irrespective of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA conducts a rigorous review of proposed product names, and may reject a product name if it believes that the name inappropriately implies medical claims or if it poses the potential for confusion with other product names. For example, the FDA previously rejected our proposed product name, Acetavance, based on the agency's assertion that the name is unacceptable from a promotional perspective. Following that rejection, we submitted alternative product names to the agency for review, and have recently been informed by the agency that the trade name, Ofirmev, is acceptable. However, the FDA will not approve this trade name until the NDA for intravenous acetaminophen is approved. If the FDA determines that the trade names of other products that are approved prior to the approval of intravenous acetaminophen may present a risk of confusion with our proposed trade name, the FDA may not ultimately approve Ofirmev. If our trade name, Ofirmev, is rejected, we will lose the benefit of any brand equity that may already have been developed for this product candidate, as well as the benefit of our existing trademark applications for this trade name. Additionally, if the FDA does not approve one of our alternative product names for intravenous acetaminophen prior to the NDA approval date, we may be required to launch this product candidate without a brand name, and our efforts to build a successful brand identity for, and commercialize, this product candidate may be adversely impacted.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

Numerous legislative and regulatory proposals are aimed at changing the healthcare system and pharmaceutical industry, including proposals designed to reduce the cost of prescription products, change the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products, permit re-importation of pharmaceutical products into the U.S., and proposals concerning various safety matters. For example, in an attempt to protect against counterfeit drugs, the federal government and numerous states have enacted pedigree legislation. In particular, California has enacted legislation that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. California's electronic pedigree requirement is scheduled to take effect in January 2011. Compliance with California and future federal or state electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens. It is also possible that other proposals will be adopted. For example, legislation has been proposed to reform the U.S. healthcare system with an objective of ultimately reducing healthcare costs by, among other things, limiting the level of reimbursement for pharmaceuticals. The enactment of any cost containment measures could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our research and development efforts. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions, and any failure to comply with those obligations could subject us to penalties and sanctions, which could in turn have a material adverse effect on our business and financial condition.

As a condition of reimbursement by various federal and state healthcare programs, we must calculate and report certain pricing information to federal and state healthcare agencies. The regulations regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates and other governmental programs are complex. Our calculations and methodologies are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. In addition, because

our processes for these calculations and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to the risk of errors. Any failure to comply with the government reporting and payment obligations could result in civil and/or criminal sanctions.

We may never receive approval to commercialize Ofirmev or any other product candidates we may acquire outside of the U.S.

Our rights to Ofirmev are limited to the U.S. and Canada. In order to market Ofirmev and any product candidates we may acquire in Canada or other jurisdictions outside of the U.S., we must comply with numerous and varying regulatory requirements of other countries regarding non-clinical testing, manufacturing, safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that our products may not be approved for all indications requested, which could limit the uses of our products and have an adverse effect on product sales and potential royalties, and that any regulatory approvals we may obtain may be subject to limitations on the indicated uses for which our products may be marketed or require us to perform costly, post-marketing follow-up studies.

Public concern regarding the safety of drug products such as Ofirmev could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government’s clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving Ofirmev, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of Ofirmev, the indications for which this product candidate is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize Ofirmev may be otherwise adversely impacted.

We expect intense competition for Ofirmev, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of Ofirmev from academic

institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render Ofirmev obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render Ofirmev obsolete or noncompetitive.

Ofirmev will compete with well-established products with similar indications. Competing products available for the treatment of pain include opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the U.S. from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, was approved by the FDA in June 2009 for the treatment of pain and fever in adults. Competing products available for the treatment of fever in the hospital setting include acetaminophen administered orally and rectally, aspirin and NSAIDs, which may be administered orally, topically or intravenously. Additional products may be developed for the treatment of acute pain, including new injectable NSAIDs, novel opioids, new formulations of currently available opioids and NSAIDS, long-acting local anesthetics and new chemical entities as well as alternative delivery forms of various opioids and NSAIDs.

Competitors may seek to develop alternative formulations of intravenous acetaminophen for our targeted indications that do not directly infringe on our in-licensed patent rights. For example, we are aware of several U.S. and Canadian patents and patent applications covering various potential injectable formulations of acetaminophen, including intravenous formulations, as well as methods of making and using these potential formulations. The commercial opportunity for Ofirmev could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize Ofirmev. Our competitors may also develop drugs that are more effective, useful and less costly than ours and may be more successful than us in manufacturing and marketing their products. We expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize Ofirmev in Canada.

If Ofirmev does not achieve broad market acceptance, the revenues that we generate from its sales will be limited.

The commercial success of Ofirmev, if approved, will depend upon its acceptance by the medical community, our ability to ensure that the drug is included in hospital formularies, and coverage and reimbursement for Ofirmev by third-party payors, including government payors. The degree of market acceptance of Ofirmev or any other product candidate we may license or acquire will depend on a number of factors, including:

- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for Ofirmev that may be more restrictive than oral formulations of acetaminophen;

- changes in the standard of care for the targeted indications for our product candidates, which could reduce the marketing impact of any superiority claims that we could make following FDA approval; and
- potential advantages over, and availability of, alternative treatments, including, in the case of Ofirmev, a number of products already used to treat pain or fever in the hospital setting.

Our ability to effectively promote and sell Ofirmev and any other product candidates we may license or acquire in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and achieve acceptance of the product onto hospital formularies, as well as our ability to obtain sufficient third-party coverage or reimbursement. Since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers in the hospital marketplace will also depend on our ability to effectively promote our product candidates to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

We have never marketed a drug before, and if we are unable to establish an effective commercial infrastructure, we will not be able to successfully commercialize Ofirmev.

We are planning to build our own sales and marketing capabilities in order to market Ofirmev directly to physicians, nurses, hospitals, group purchasing organizations and third-party payors. The development of a hospital-focused sales, marketing and distribution infrastructure for our domestic operations will be expensive and time consuming and, if not completed on time, could delay the launch of Ofirmev, if approved, and may otherwise negatively impact our commercialization efforts. If we are not successful in attracting or retaining a full complement of qualified sales and marketing personnel in time for the launch of this product candidate, we may not achieve our initial sales objectives. We will incur significant additional expenses associated with the recruitment, training and compensation of our new sales representatives and, because we have elected to begin hiring key sales and marketing management personnel and implementing other pre-commercialization activities prior to the date on which we know whether Ofirmev will be approved, we will incur significant commercialization costs for this product candidate before we know when, or if, it will be approved. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate any product revenue, may experience increased expenses, and may never become profitable.

We will rely on third parties to perform many essential services for any products that we commercialize, including services related to warehousing and inventory control, distribution, customer service, accounts receivable management, cash collection and adverse event reporting, and if such third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize Ofirmev will be significantly impacted and we may be subject to regulatory sanctions.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of Ofirmev, key aspects of which will be out of our direct control. These service providers will provide key services related to warehousing and inventory control, distribution, customer service, accounts receivable management and cash collection, and, as a result, most of our inventory will be stored at a single warehouse maintained by one such service provider. We will substantially rely on this provider as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to

meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we have engaged third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidate and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, we could be subject to regulatory sanctions.

If the government or third-party payors fail to provide coverage and adequate coverage and payment rates for Ofirmev or any future products we may license or acquire, if any, or if hospitals choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. In particular, many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to our product candidates. Accordingly, Ofirmev or any other product candidates that we may in-license or acquire, if approved, will face competition from other therapies and drugs for these limited hospital financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Governments continue to propose and pass legislation designed to reduce the cost of healthcare. In some foreign markets, such as Canada, the government controls the pricing of prescription pharmaceuticals. In these countries, pricing negotiated with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. In the U.S., we expect that there will be an increase in federal and state proposals to implement pricing controls for prescription drugs, and new legislation and regulations affecting the pricing of pharmaceuticals might change before our product candidates are approved for marketing. For example, the U.S. Congress is considering a number of legislative and regulatory proposals with an objective of ultimately reducing healthcare costs. Legislative and regulatory actions under consideration in the U.S. include health care reform initiatives that could significantly alter the market for pharmaceuticals (such as private health insurance expansion, the creation of competing public health insurance plans, a variety of proposals that would reduce government expenditures for prescription drugs to help finance healthcare reform, or the eventual transition of the U.S. multiple payer system to a single payer system). Other actions under consideration include proposals for government intervention in pharmaceutical pricing, changes in government reimbursement, an accelerated approval process for “follow-on” biologics, legalization of commercial drug importation into the U.S., and involuntary approval of medicines for over-the-counter, or OTC, use. Such legislation could result in the exclusion of Ofirmev and any other product candidates we may license or acquire from coverage and reimbursement programs, or lower the prices we would receive for our product candidates. Our revenues from the sale of any approved products could be significantly reduced as a result of these cost containment measures and reforms, which would negatively impact our profitability.

If we breach any of the agreements under which we license rights to Ofirmev from others, we could lose the ability to continue to develop and commercialize this product candidate.

In March 2006, we entered into an exclusive license agreement with BMS relating to Ofirmev for the U.S. and Canada. Because we have in-licensed the rights to this product candidate from a third party, if there is any dispute between us and our licensor regarding our rights under our license agreement, our ability to develop and

commercialize this product candidate may be adversely affected. Any uncured, material breach under our license agreement could result in our loss of exclusive rights to our product candidate and may lead to a complete termination of our related product development efforts.

If BMS breaches the underlying agreement under which we sublicense the rights to Ofirmev, we could lose the ability to develop and commercialize this product candidate.

Our license for Ofirmev is subject to the terms and conditions of a license from SCR Pharmatop to BMS, under which BMS originally licensed the intellectual property rights covering Ofirmev. If BMS materially breaches the terms or conditions of this underlying license from SCR Pharmatop, and neither BMS nor we adequately cure that breach, or BMS and SCR Pharmatop otherwise become involved in a dispute, the breach by BMS or disputes with SCR Pharmatop could result in a loss of, or other material adverse impact on, our rights under our license agreement with BMS. While we would expect to exercise all reasonable rights and remedies available to us, including seeking to cure any breach by BMS, and otherwise seek to preserve our rights under the patents licensed by SCR Pharmatop, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the license from SCR Pharmatop to BMS could result in our loss of exclusive rights to our Ofirmev product candidate and may lead to a complete termination of our product development and any commercialization efforts for Ofirmev.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of February 1, 2010, we had 90 employees. We will need to substantially expand our managerial, commercial, financial and other personnel resources in order to manage our operations and prepare for the commercialization of Ofirmev, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth, and we may not be able to recruit and retain qualified personnel in the future, particularly for sales and marketing positions, due to competition for personnel among pharmaceutical businesses, and the failure to do so could have a significant negative impact on our future product revenues and business results. Our need to effectively manage our operations, growth and various projects requires that we:

- continue the hiring and training of an effective commercial organization in anticipation of the potential approval of Ofirmev, and establish appropriate systems, policies and infrastructure to support that organization;
- ensure that our consultants and other service providers successfully carry out their contractual obligations, provide high quality results, and meet expected deadlines;
- continue to carry out our own contractual obligations to our licensors and other third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California area. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the product acquisition, development, regulatory and commercialization expertise of our senior management, particularly Theodore R. Schroeder, our President and Chief Executive Officer, James B. Breitmeyer, M.D., Ph.D., our Executive Vice President, Development and Chief Medical Officer, William R. LaRue, our Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary, and Scott A. Byrd, our Senior Vice President and Chief Commercial Officer. If we lose one or more of these key employees, our ability to successfully implement our business strategy could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel. Although we have employment agreements with Mr. Schroeder, Dr. Breitmeyer, Mr. LaRue and Mr. Byrd, these agreements are terminable at will at any time with or without notice and, therefore, we may not be able to retain their services as expected.

In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for Ofirmev or other product candidates we may license or acquire and may have to limit their commercialization.

The use of Ofirmev and any other product candidates we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- decreased demand for our product candidates;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials with a $15.0 million annual aggregate coverage limit. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our future growth depends on our ability to identify and acquire or in-license products and if we do not successfully identify and acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.

We in-licensed the rights to Ofirmev from a third party who conducted the initial development of this product candidate, which is currently our only product candidate. An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on the hospital marketplace. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies in the current economic environment;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

Our business involves the use of hazardous materials and we and our third-party manufacturer must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturer's activities and, to a lesser extent, our own activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidate and other hazardous compounds. We and our manufacturer are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations

could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for Ofirmev could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidate may be delayed.

Risks Related to Intellectual Property

The patent rights that we have in-licensed covering Ofirmev are limited to a specific intravenous formulation of acetaminophen, and our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient itself and other formulations that may be developed by competitors.

The active ingredient in Ofirmev is acetaminophen. Patent protection for the acetaminophen molecule itself in the territories licensed to us, which include the U.S. and Canada, is not available. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as Ofirmev so long as the competitors do not infringe any process or formulation patents that we have in-licensed from BMS and its licensor, SCR Pharmatop. We are aware of a number of third-party patents in the U.S. that claim methods of making acetaminophen. If a supplier of the API for our Ofirmev product candidate is found to infringe any of these method patents covering acetaminophen, our supply of the API could be delayed and we may be required to locate an alternative supplier. We are also aware of several U.S. and Canadian patents and patent applications covering various potential injectable formulations of acetaminophen as well as methods of making and using these potential formulations. For example, Injectapap, a liquid formulation of acetaminophen for intramuscular injection, was approved by the FDA for the reduction of fever in adults in March 1986, although it was subsequently withdrawn from the market by McNeil Pharmaceutical in July 1986.

The number of patents and patent applications covering products in the same field as Ofirmev indicates that competitors have sought to develop and may seek to market competing formulations that may not be covered by our licensed patents and patent applications. In addition, the Canadian patent applications that we have in-licensed have yet to be examined by the Canadian Patent Office. Thus, they may issue with claims that cover less than the corresponding in-licensed U.S. patents, or simply not issue at all. The commercial opportunity for Ofirmev could be significantly harmed if competitors are able to develop an alternative formulation of acetaminophen outside the scope of our in-licensed patents.

If Ofirmev is approved by the FDA, one or more third parties may challenge the patents covering this product, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug product containing acetaminophen and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for Ofirmev; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-party's generic drug product. A certification that the new product will not infringe the Orange Book-listed patents for Ofirmev, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third-party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay. Litigation or other proceedings to enforce or defend

intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products.

We depend on our licensors for the maintenance and enforcement of our intellectual property and have limited control, if any, over the amount or timing of resources that our licensors devotes on our behalf, or whether any financial difficulties experienced by our licensors could result in their unwillingness or inability to secure, maintain and enforce patents protecting our intellectual property.

We depend on our licensor, BMS, and its licensor SCR Pharmatop, to protect the proprietary rights covering Ofirmev and we have limited, if any, control over the amount or timing of resources that BMS or SCR Pharmatop devote on our behalf, or the priority they place on, maintaining patent rights and prosecuting patent applications to our advantage.

Either BMS or SCR Pharmatop, depending on the patent or application, is responsible for maintaining issued patents and prosecuting patent applications. SCR Pharmatop is under a contractual obligation to BMS to diligently prosecute their patent applications and allow BMS the opportunity to consult, review and comment on patent office communications. However, we cannot be sure that SCR Pharmatop will perform as required. Should BMS decide it no longer wants to maintain any of the patents licensed to us, BMS is required to afford us the opportunity to do so at our expense. However, we cannot be sure that BMS will perform as required. If BMS does not perform, and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights. Moreover, either BMS or SCR Pharmatop may experience serious difficulties related to their overall business or financial stability, and they may be unwilling or unable to continue to expend the financial resources required to maintain and prosecute these patents and patent applications. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors to protect a substantial portion of our proprietary rights. BMS has the first right to prosecute a third-party infringement of the SCR Pharmatop patents, and has the sole right to prosecute third-party infringement of the BMS patents. We will have the ability to cooperate with BMS in third-party infringement suits involving the SCR Pharmatop patents. It is possible that SCR Pharmatop or BMS could take some action or fail to take some action that could harm the SCR Pharmatop patents. In certain instances, we may be allowed to pursue the infringement claim ourselves.

Our licensors may also be notified of alleged infringement and be sued for infringement of third-party patents or other proprietary rights. We may have limited, if any, control or involvement over the defense of these claims, and our licensors could be subject to injunctions and temporary or permanent exclusionary orders in the U.S. or other countries. Our licensors are not obligated to defend or assist in our defense against third-party claims of infringement. We have limited, if any, control over the amount or timing of resources, if any, that our licensors devote on our behalf or the priority they place on defense of such third-party claims of infringement.

For a third-party challenge to the SCR Pharmatop in-licensed patents relating to Ofirmev, we will have some ability to participate in either SCR Pharmatop's or BMS' defense thereof. In the case that neither party elects to defend the third-party challenge, we may have the opportunity to defend it. For a third-party challenge to the in-licensed BMS patents relating to Ofirmev, BMS has the sole right to defend such challenge. If it chooses not to defend such challenge, we may have the right to renegotiate or terminate the license regarding the in-licensed BMS patents.

Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we or our licensors may not be successful in defending claims of intellectual property infringement by third parties, which could have a material adverse affect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management.

Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for Ofirmev or any other product candidates that we may license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the U.S. The patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our product candidates or technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the issued patents covering our product candidates may not provide a basis for commercially viable active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- patents of others may have an adverse effect on our business.

Patent applications in the U.S. are maintained in confidence for at least 18 months after their earliest effective filing date. Consequently, we cannot be certain that our licensors were the first to invent or the first to file patent applications on our product candidates. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. Even if patents issue, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us.

We also rely on trade secrets to protect our technology, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our licensors, employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If our licensors or we fail to obtain or maintain patent protection or trade secret protection for Ofirmev or any other product candidate we may license or acquire, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and sell Ofirmev or any other product candidates that we may license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of pain treatment and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse affect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that Ofirmev may infringe. There could also be existing patents of which we are not aware that Ofirmev may inadvertently infringe.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe on their products or technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management’s attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor’s patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these

employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Finances and Capital Requirements

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We are a development stage company with a limited operating history. We have focused primarily on in-licensing and developing Ofirmev and our former product candidate, omiganan pentahydrochloride, with the goal of supporting regulatory approval for these product candidates. We have incurred losses in each year since our inception in May 2004, including net losses of $45.5 million, $57.1 million and $51.7 million for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009, we had an accumulated deficit of $ 217.0 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. For example, our development expenses decreased in 2009 due to the completion of our clinical development program for Ofirmev, and the discontinuation of our development program for our omiganan pentahydrochloride product candidate. However, we incurred increased pre-commercialization expenses during 2009 as we prepared for the potential market launch of Ofirmev, and we expect to incur significant sales, marketing and outsourced manufacturing expenses, as well as continued development expenses related to the commercialization of this product, if approved by the FDA. As a result, we expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We currently have no source of revenue and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain regulatory approval for Ofirmev, or any other product candidates that we may license or acquire;
- manufacture commercial quantities of Ofirmev, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell Ofirmev, if it is approved.

If Ofirmev is approved for commercial sale, we anticipate incurring significant costs associated with its commercialization. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated in May 2004 and have only been conducting operations with respect to Ofirmev since March 2006 and our discontinued omiganan pentahydrochloride product candidate since July 2004. Our operations to date have been limited to organizing and staffing our company, in-licensing and conducting product development activities, including clinical trials and manufacturing development activities, for Ofirmev and omiganan pentahydrochloride. Further, in 2009 we began to establish our commercial infrastructure for Ofirmev. We have not yet demonstrated an ability to obtain regulatory approval for or successfully commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

We will need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing products for use in the hospital setting, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We will need to raise additional capital to:

- fund our operations and continue our efforts to hire additional personnel and build a commercial infrastructure to prepare for the commercialization of Ofirmev, if approved by the FDA;
- qualify and outsource the commercial-scale manufacturing of our products under current good manufacturing practices; and
- in-license and develop additional product candidates.

In February 2009, we completed a private placement of common stock and warrants to purchase common stock, raising net proceeds of approximately $86.2 million. We believe that with our currently available cash and cash equivalent balance, we have sufficient funds to meet our projected operating requirements through the next twelve months. We have based this estimate on assumptions that may prove to be wrong and we could spend our available financial resources faster than we currently expect. Further, we may not have sufficient financial resources to meet all of our objectives if Ofirmev is approved, which could require us to postpone, scale back or eliminate some, or all, of these objectives, including our potential launch activities. Our future funding requirements will depend on many factors, including, but not limited to:

- the potential for delays in our efforts to seek regulatory approval for Ofirmev, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute Ofirmev;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of Ofirmev from our contract manufacturers in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if Ofirmev is approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of intravenous acetaminophen; and
- the success of the commercialization of Ofirmev.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- whether the FDA requires us to complete additional, unanticipated studies, tests or other activities prior to approving Ofirmev, which would likely further delay any such approval;
- if Ofirmev is approved, our ability to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;
- our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our future development programs;
- any product liability or intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting Ofirmev or the product candidates of our competitors; and
- if Ofirmev receives regulatory approval, the level of underlying hospital demand for this product candidate and wholesalers' buying patterns.

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

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

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. If we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. For example, in February 2006, we entered into a $7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation, and in December 2007, we amended this agreement and secured an additional $15.0 million loan from the same parties and GE Business Financial Services Inc. Our amended loan and security agreement contains a variety of affirmative and negative covenants, including required financial reporting, limitations on the disposition of assets other than in the ordinary course of business, limitations on the incurrence of additional debt and other requirements. To secure our performance of our obligations under our amended loan and security agreement, we pledged substantially all of our assets other than

intellectual property assets, to the lenders. Our failure to comply with the covenants in the amended loan and security agreement could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

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

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

The use of our net operating loss carryforwards and research tax credits may be limited.

Our net operating loss carryforwards and research and development tax credits may expire and not be used. As of December 31, 2009, we have generated federal and state net operating loss carryforwards of approximately $171.4 million and $170.6 million, respectively. We also have federal and state research and development tax credit carryforwards of approximately $3.8 million and $1.9 million, respectively. Our net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2014 for state purposes if we have not used them prior to that time, and our federal tax credits will begin expiring in 2024 unless previously used. Our state tax credits carryforward indefinitely. Additionally, our ability to use any net operating loss and credit carryforwards to offset taxable income in the future will be limited under Internal Revenue Code Sections 382 and 383 if we have a cumulative change in ownership of more than 50% within a three-year period. We have not completed an analysis as to whether such a change of ownership has occurred, but in such an event, may be limited to the amount of net operating loss carryforwards and research tax credits that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. In addition, California and certain states have suspended use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact on our operating results and financial condition.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

Risks Relating to Securities Markets and Investment in Our Stock

There may not be a viable public market for our common stock.

Our common stock had not been publicly traded prior to our initial public offering, which was completed in October 2006, and an active trading market may not be sustained. We have never declared or paid any cash dividends on our capital stock, and we currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock for the foreseeable future. Furthermore, our amended loan and security agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc. restricts our ability to pay cash dividends. Therefore, investors will have to rely on appreciation in our stock price and a liquid trading market in order to achieve a gain on their investment.

Our stock may be subject to substantial price and volume fluctuations due to a number of factors, many of which are beyond our control and may prevent our stockholders from reselling our common stock at a profit.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. For example, the volatility in the overall capital markets reached unprecedented levels during 2008 and 2009, which affected most equity securities. Similar market volatility could reduce the market price of our common stock in spite of our operating performance. Further, high stock price volatility could result in higher stock-based compensation expense.

The trading prices for our common stock during the 52 weeks ending December 31, 2009 ranged from a high of $12.68 to a low of $5.68. The market price of our common stock is likely to continue to be highly volatile and may fluctuate substantially due to many factors, including:

- announcements concerning the progress of our efforts to obtain regulatory approval for and commercialize Ofirmev, including any requests we receive from the FDA for additional studies or data that result in delays in obtaining regulatory approval or launching this product candidate, if approved;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of Ofirmev, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;

- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

The realization of any of the risks described in these "Risk Factors" could have a dramatic and material adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of our management's attention and resources, which could hurt our business, operating results and financial condition.

Future sales of our common stock may cause our stock price to decline.

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock that they may now be able to sell in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, the holders of a substantial number of shares of common stock may have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

For example, in May 2009, we completed the registration of 18,059,691 shares of our common stock in connection with a financing transaction completed in February 2009. As a result, all of the shares currently outstanding may generally be freely sold in the public market, subject to volume and other limitations applicable to our affiliates. Additionally, in September 2009, we filed with the U.S. Securities and Exchange Commission, or SEC, a registration statement for $100.0 million of debt securities, preferred stock, common stock, debt warrants and equity warrants, which was subsequently declared effective by the SEC. We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws.

In addition, certain of our officers have established, and other of our directors and executive officers may in the future establish, programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Our executive officers and directors and their affiliates may exercise control over stockholder voting matters in a manner that may not be in the best interests of all of our stockholders.

As of December 31, 2009, our executive officers and directors and their affiliates together controlled approximately 50.9% of our outstanding common stock. As a result, these stockholders will collectively be able to significantly influence all matters requiring approval of our stockholders, including the election of directors

and approval of significant corporate transactions. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets, and might affect the prevailing market price of our common stock.

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

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

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations;
- a requirement of approval of not less than 66²/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval.

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

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

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Furthermore, our amended loan and security agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc., restricts our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad

market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

Item 1B. ***Unresolved Staff Comments***

Not applicable.

Item 2. ***Properties***

We lease approximately 23,494 square feet of space in our headquarters in San Diego, California under a sublease that expires in 2012. We have no laboratory, research or manufacturing facilities; however we do own manufacturing equipment which is located at our third-party contractors. We currently do not plan to purchase or lease facilities for manufacturing, packaging or warehousing, as such services are provided to us by third-party contractors. We believe that our current facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. ***Legal Proceedings***

We are not engaged in any legal proceedings.

Item 4. ***Reserved***

Not applicable.

PART II

Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

Market Information

Our common stock has been traded on the NASDAQ Global Market since October 25, 2006 under the symbol "CADX." Prior to that time, there was no public market for our common stock. As of February 28, 2010, there were 50,512,429 shares of common stock outstanding held by approximately 50 stockholders of record. Many stockholders hold their shares in street name. We believe that there are more than 2,000 beneficial owners of our common stock. The closing price of our common stock on the NASDAQ Global Market on December 31, 2009 was $9.67 per share. The following table sets forth the high and low sales prices for our common stock as reported on the NASDAQ Global Market for the periods indicated:

	Year Ended December 31,			
	2009		2008	
	High	Low	High	Low
Period:				
First Quarter	$ 9.69	$5.68	$15.00	$4.84
Second Quarter	$11.52	$8.25	$ 7.85	$5.71
Third Quarter	$12.68	$9.37	$12.01	$6.00
Fourth Quarter	$11.76	$8.40	$ 9.06	$4.39

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2009, about our common stock that may be issued upon the exercise of stock options and the vesting of restricted stock units granted to employees, consultants and members of our board of directors under all existing equity compensation plans including our 2006 Equity Incentive Award Plan and our 2004 Equity Incentive Award Plan. The 2006 Equity Incentive Award Plan was adopted at the time of our initial public offering in October 2006 which coincided with the discontinuance of the 2004 Equity Incentive Award Plan. See Note 9 to the Notes to Financial Statements in Item 8 of this Annual Report on Form 10-K for further discussion of our equity plans.

Equity Compensation Plan Information

	Number of securities to be issued upon exercise of outstanding options, restricted stock units, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Plan Category:			
Equity compensation plans approved by security holders	5,367,488[1]	$ 7.32[2]	687,224[3]
Equity compensation plans not approved by security holders.	—	—	—
Total.	5,367,488	$ 7.32	687,224[3]

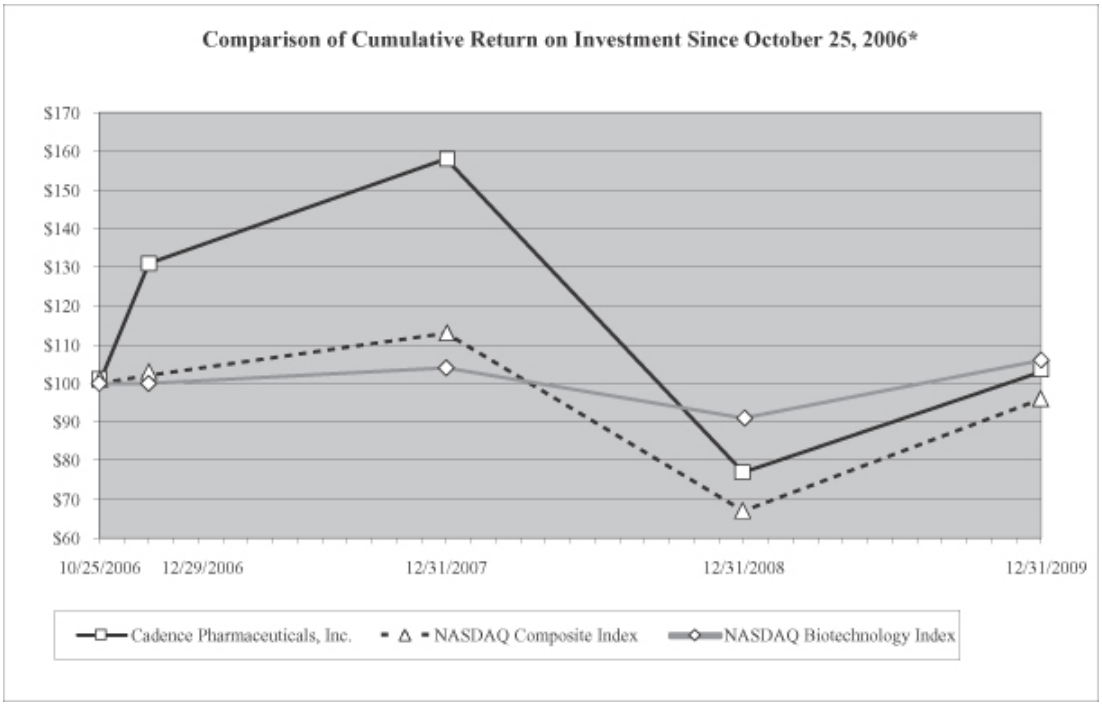
(1) Of these shares of common stock, 3,711,457 shares were subject to outstanding options under the 2006 Equity Incentive Award Plan and 1,506,281 shares were subject to outstanding options under the 2004 Equity Incentive Award Plan. In addition, 149,750 of the shares were subject to outstanding restricted stock units under the 2006 Equity Incentive Award Plan.

(2) As restricted stock units do not have an exercise price, the weighted average exercise price does not take into account the 149,750 restricted stock units granted under the 2006 Equity Incentive Award Plan.

(3) The 2006 Equity Incentive Award Plan contains an "evergreen" provision which allows for annual increases in the number of shares available for future issuance on January 1 of each year during the ten-year term of the plan, beginning on January 1, 2008. The annual increase in the number of shares shall be equal to the lesser of (i) 4% of our outstanding common stock on the applicable January 1 or (ii) such lesser amount determined by our board of directors. At January 1, 2009 and 2008, the board of directors approved the amount of shares authorized for future issuance under the 2006 Plan to be increased by 1,269,576 shares and 1,018,939 shares, respectively, under this provision.

Performance Graph

The following stock performance graph illustrates a comparison of the total cumulative stockholder return on our common stock since October 25, 2006, which is the date our common stock first began trading on the NASDAQ Global Market, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on October 25, 2006, and that all dividends were reinvested.



	10/25/2006	12/29/2006	12/31/2007	12/31/2008	12/31/2009
Cadence Pharmaceuticals, Inc.	$ 100	$ 131	$ 158	$ 77	$ 103
NASDAQ Composite Index	$ 100	$ 102	$ 113	$ 67	$ 96
NASDAQ Biotechnology Index	$ 100	$ 100	$ 104	$ 91	$ 106

* No cash dividends have been declared or paid on our common stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our common stock. We expect to retain future earnings, if any, to fund the

development and growth of our business. The payment of dividends by us on our common stock is limited by our loan and security agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

Issuer Repurchases of Equity Securities

Not applicable.

Item 6. ***Selected Financial Data***

The selected financial data set forth below is derived from our audited financial statements and may not be indicative of future operating results. Audited balance sheets at December 31, 2009 and 2008 and the related audited statements of operations and of cash flows for each of the three years in the period ended December 31, 2009 and notes thereto appear elsewhere in this Annual Report on Form 10-K. Audited balance sheets at December 31, 2007, 2006 and 2005 and the related audited statements of operations and of cash flows for 2006 and 2005 are not included elsewhere in this Annual Report on Form 10-K.

The following selected financial data should be read in conjunction with the financial statements, related notes and other financial information appearing elsewhere in this Annual Report on Form 10-K. Amounts are in thousands, except share and per share amounts.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
Statement of Operations Data:					
Research and development	$ 19,464	$ 40,018	$ 41,781	$ 47,827	$ 6,126
Sales and marketing	11,729	2,984	2,866	810	240
General and administrative	12,891	11,146	9,587	4,946	1,412
Other	413	2,384	—	—	—
Loss from operations	(44,497)	(56,532)	(54,234)	(53,583)	(7,778)
Interest income	182	1,530	3,404	1,945	255
Interest expense	(1,137)	(1,916)	(867)	(498)	—
Other expense	(39)	(180)	(17)	(37)	(183)
Net loss	$(45,491)	$(57,098)	$(51,714)	$(52,173)	$(7,706)
Basic and diluted net loss per share[1]	$ (0.93)	$ (1.55)	$ (1.81)	$ (10.07)	$ (6.67)

(1) As a result of the issuance of 6,900,000 shares of common stock in our initial public offering in the fourth quarter of 2006 and the conversion of our preferred stock into 19,907,605 shares of common stock upon completion of our initial public offering, the issuance of 9,240,307 shares of common stock pursuant to an effective shelf registration in the first quarter of 2008 and the issuance of 12,039,794 shares of common stock pursuant to a private placement in the first quarter of 2009, there is a lack of comparability in the per share amounts between the periods presented. Please see Note 2 to the Notes to Financial Statements in Item 8 of this Annual Report on Form 10-K for further discussion.

	As of December 31,				
	2009	2008	2007	2006	2005
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 82,006	$ 47,627	$ 55,393	$ 86,826	$ 15,025
Working capital	67,193	28,385	36,839	76,203	14,405
Total assets	92,563	55,148	64,612	93,092	15,891
Long-term debt, less current portion and discount	—	6,098	13,412	4,433	—
Deficit accumulated during the development stage	(217,019)	(171,528)	(114,429)	(62,716)	(10,543)
Total stockholders' equity	75,063	26,440	28,458	75,409	14,745

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

You should read the following discussion and analysis together with "Item 6—Selected Financial Data" and the financial statements and related notes included in "Item 8—Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. This discussion may contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in any forward-looking statements as a result of many factors, including those set forth in this Annual Report on Form 10-K in "Item 1A. Risk Factors."

Overview

We are a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. Since our inception in May 2004, we have in-licensed rights to two late-stage product candidates, Ofirmev™, a proprietary intravenous formulation of acetaminophen, and omiganan pentahydrochloride 1% aqueous gel, a product candidate which we have since discontinued. We intend to build a leading franchise in the hospital setting, continuing to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations.

Background

We were incorporated in May 2004 and during that year we focused on hiring our management team and initial operating employees, but substantial operations did not commence until September 2004. Since that time, we have in-licensed rights to two late-stage product candidates.

Ofirmev™

In March 2006, we in-licensed rights to Ofirmev, a proprietary intravenous formulation of acetaminophen, from BMS, which currently markets the product in Europe and several other markets under the brand name Perfalgan. In October 2006, we initiated our Phase III clinical development program for this product candidate for the management of pain and reduction of fever in adults and children. In May 2009, we completed our clinical development program for Ofirmev and submitted an NDA to the FDA, requesting marketing approval of Ofirmev for the management of pain and reduction of fever in adults and children. Our NDA was accepted for filing by the FDA and designated for priority review in July of that year. Pursuant to Prescription Drug User Fee Act, or PDUFA, guidelines, the FDA was expected to complete its review and provide an action letter with respect to the NDA in November 2009; however, the agency instead indicated that its review would be extended for up to three additional months, resulting in a new PDUFA goal date in February 2010.

On February 10, 2010, we received a complete response letter from the FDA, which stated that the NDA could not be approved in its present form due to deficiencies with respect to good manufacturing practices observed during the agency's inspection of the facilities of our third-party manufacturer, which was completed on February 5, 2010. In the complete response letter, the FDA did not indicate that the completion of any additional clinical trials were required in order to approve the NDA for Ofirmev and did not cite any safety or efficacy deficiencies. On February 18, 2010, our third-party manufacturer submitted a response to the FDA, and we intend to re-submit a 505(b)(2) NDA for Ofirmev as soon as possible following the resolution of the inspectional observations.

We believe that, if approved by the FDA, Ofirmev may fulfill significant unmet needs in the hospital setting. We also believe that the hospital pharmaceuticals market is both concentrated and underserved and intend to focus our sales and marketing efforts primarily on hospital-based physicians who manage patients with mild to severe pain who cannot take oral medications.

Omiganan pentahydrochloride

In 2005, we completed a special protocol assessment, or SPA, for omiganan pentahydrochloride 1% aqueous gel, and initiated Phase III clinical trials for this product candidate. In March 2009, we announced that our Phase III clinical trial of omiganan pentahydrochloride did not meet its primary endpoint and discontinued our development efforts for this product candidate because we believed that the results of the study did not support applications for marketing approval. At the same time, we implemented cost reduction measures and restructured our operations to make additional resources available for our Ofirmev development program and other operating activities.

We are a development stage company and we have incurred significant net losses since our inception. As of December 31, 2009, we had an accumulated deficit of $217.0 million. These losses have resulted principally from costs incurred in connection with research and development activities, including license fees, costs of clinical trial activities associated with our product candidates, pre-commercialization manufacturing development activities, the establishment of our commercial infrastructure and general and administrative expenses. We expect to continue to incur operating losses for the foreseeable future as we commercialize Ofirmev, if approved by the FDA, and acquire or in-license additional products, technologies or businesses that are complementary to our own.

We have financed our operations primarily through the issuance of equity securities in both public and private offerings. In October 2006, we completed an initial public offering in which we sold 6.0 million shares of our common stock at $9.00 per share and received aggregate net proceeds of $48.4 million (after underwriting discounts and offering costs). In November 2006, following exercise of the underwriters' over-allotment option, we sold 0.9 million shares of our common stock at $9.00 per share and received aggregate net proceeds of $7.5 million (after underwriting discounts). In February 2008, we completed a registered direct offering pursuant to an effective shelf registration statement under which we issued and sold 9.2 million shares of common stock at $5.34 per share and received aggregate net proceeds of approximately $49.1 million (after offering costs). In February 2009, we raised additional funds by completing a private placement of approximately 12.0 million shares of common stock at a price of $7.13 per share, and warrants to purchase up to approximately 6.0 million additional shares of common stock at a price of $0.125 per warrant, for aggregate net proceeds of $86.2 million (after offering costs). Each warrant has a five-year term and is exercisable in cash or by net exercise for one share of common stock at a price of $7.84. As of December 31, 2009, all of the warrants remain outstanding.

Revenues

We have not generated any revenues to date, and we do not expect to generate any revenues from licensing, achievement of milestones or product sales until we are able to commercialize our Ofirmev product candidate ourselves or execute a collaboration arrangement with a third party.

Research and Development Expenses

Our research and development expenses consist primarily of license fees, salaries and related employee benefits, costs associated with clinical trials managed by our contract research organizations, or CROs, costs associated with non-clinical activities, such as regulatory expenses, and pre-commercialization manufacturing development activities. The clinical trial expenses include payments to vendors such as CROs, investigators, clinical suppliers and related consultants. License fees are paid to the patent holders of our product candidates that give us the exclusive licenses to the patent rights and know-how for selected indications and territories. Manufacturing development activities include the costs to develop facilities for the commercial production of our drug products prior to approval, the production of supply and validation lots, and other manufacturing support activities related to the requirements for submitting NDAs for our product candidates.

Our historical research and development expenses relate predominantly to Ofirmev and our discontinued omiganan pentahydrochloride product candidate. We have expensed these charges as they have been incurred as

the underlying technology associated with these expenditures relates to our research and development efforts and has no alternative future uses. A substantial portion of these external costs are tracked on a project basis. However, our internal research and development resources are used in several projects and may not be attributable to a specific product candidate. For example, a substantial portion of our internal costs, including personnel and facility related costs, is not tracked on a project basis. We have summarized these costs in the following table. Costs that are not attributable to a specific product candidate, including salaries and related personnel costs, are included in the "other supporting costs" category (in thousands):

	Year Ended December 31,			Period from May 26, 2004 (Inception) through December 31, 2009
	2009	2008	2007	
Ofirmev[1]	$ 7,014	$15,234	$14,107	$ 64,407
Omiganan pentahydrochloride[2][3]	1,663	14,809	20,191	57,459
Other supporting costs	10,787	9,975	7,483	35,234
	$19,464	$40,018	$41,781	$ 157,100

(1) We paid an up-front license fee of $25.0 million in 2006 for Ofirmev, which is included in the amount for the period from May 26, 2004 (inception) through December 31, 2009. We may be required to make future milestone payments totaling up to $40.0 million upon the achievement of various milestones related to regulatory and commercial events in addition to royalties on the sales of the licensed products, including payments totaling $15.0 million upon the approval of our NDA by the FDA.

(2) We paid an up-front license fee of $2.0 million in 2004 for omiganan pentahydrochloride, of which $1.5 million is included in the costs for the period from May 26, 2004 (inception) through December 31, 2009. As a result of the termination of our collaboration and license agreement with Migenix, Inc., or Migenix, on May 8, 2009, we will not be obligated to make any future milestone or royalty payments with respect to this product candidate.

(3) During the fourth quarter of 2008, we recorded an impairment charge of $2.4 million on our omiganan pentahydrochloride manufacturing equipment due to the discontinuance of our omiganan pentahydrochloride program. During 2009, we recorded adjustments to this impairment charge, reducing the charge by $0.2 million as actual costs incurred in disposing of the assets were less than anticipated. Further, in 2009 we recorded a restructuring charge of $0.6 million related to the discontinuation of its omiganan pentahydrochloride development program. These charges are presented separately on our statement of operations in "Other" operating expenses and is not included in the table above.

It is difficult to anticipate the scope and magnitude of our future research and development expenses. The FDA may require us to perform additional studies or provide other information in order to secure approval or require post-approval studies and clinical trials. Further, we plan to initiate additional clinical studies in children in an effort to obtain a six-month pediatric extension of market exclusivity for Ofirmev, if approved, and may look to expand the indications for this product candidate in the future which could require further studies. Moreover, any product candidates we may in-license or acquire in the future would likely require significant research and development resources. Therefore, we are unable to estimate with any certainty the costs we will incur in completing our development efforts for Ofirmev or any other product candidate we might acquire or in-license.

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of market research studies and pre-launch marketing activities, costs related to the establishment of our commercial infrastructure, salaries, benefits and professional fees related to building our sales and marketing capabilities. In 2009 we began to focus significant resources on establishing our commercial infrastructure in preparation for the commercial launch of Ofirmev, including by increasing our sales and marketing staff from two at the end of 2008 to 40 at the end of 2009. Further, we have been preparing to hire approximately 150 sales representatives if Ofirmev is approved by the FDA.

We anticipate our sales and marketing expenses will continue to increase as we move forward with preparations for the potential commercial launch of Ofirmev including, and if our NDA for this product candidate is approved, hiring our sales force to begin marketing Ofirmev to physicians, nurses, group purchasing organizations and third-party payors.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries, benefits and related personnel costs for our administrative, finance, human resources, legal, business development and internal systems support functions; as well as the related professional fees for these functions, insurance and facility costs. We anticipate increases in general and administrative expenses as we continue to build our corporate infrastructure and support the potential commercial operations for Ofirmev, if approved by the FDA.

Interest and Other Income and Expense

Our interest income consists primarily of interest earned on our cash, cash equivalents and short-term investments. Interest expense consists of the interest we have incurred under our amended loan and security agreement and the amortization of debt issuance costs. Other expense includes charges we have incurred to recognize other-than-temporary declines in the market value of our available-for-sale securities and the gains or losses recognized on transactions denominated in foreign currencies.

Income Taxes

We assess income tax positions and record tax benefits for all years subject to examination based upon our evaluation of the facts, circumstances and information available at the reporting date. For those tax positions where there is a greater than 50% likelihood that a tax benefit will be sustained, we have recorded the largest amount of tax benefit that may potentially be realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. For those income tax positions where there is less than 50% likelihood that a tax benefit will be sustained, no tax benefit has been recognized in the financial statements.

As of December 31, 2009, we had federal and state net operating loss carryforwards of approximately $171.4 million and $170.6 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2014 for state purposes. Additionally, we had both federal and state research and development tax credit carryforwards of approximately $3.8 million and $1.9 million, respectively. The federal tax credits will begin expiring in 2024 unless previously utilized and the state tax credits carryforward indefinitely. Under Section 382/383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards and development tax credit carryforwards that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating losses and tax credits before they expire. We have not completed a Section 382/383 study at this time to determine the impact ownership changes have had on our carryforwards. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recognized any federal or state income tax benefit in our statement of operations.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S., or GAAP, requires us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Some of our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters

that are inherently uncertain. The following accounting policies involve critical accounting estimates because they are particularly dependent on estimates and assumptions made by management about matters that are highly uncertain at the time the accounting estimates are made. In addition, while we have used our best estimates based on facts and circumstances available to us at the time, different estimates reasonably could have been used. Changes in the accounting estimates we use are reasonably likely to occur from time to time, which may have a material impact on the presentation of our financial condition and results of operations.

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

Research and Development Expenses

A substantial portion of our research and development activities is performed under agreements we enter into with external service providers, including CROs, which conduct many of our research and development activities. We accrue for costs incurred under these contracts based on factors such as estimates of work performed, milestones achieved, patient enrollment and experience with similar contracts. As actual costs become known, we adjust our accruals. To date, our accruals have been within management's estimates. Subsequent changes in estimates may result in a change in our accruals, which could also materially affect our results of operations.

Stock-Based Compensation

We account for stock-based compensation by calculating the fair value of the award on the date of grant and recognize the expense over the applicable vesting period. We calculate the fair value of stock options using the Black-Scholes pricing model, which requires a number of estimates, including the expected lives of awards, interest rates, stock volatility and other assumptions. Restricted stock units, or RSUs, are measured based on the fair market values of the underlying stock on the dates of grant. We apply a forfeiture rate to estimate the number of grants that will ultimately vest. If the awards are performance based, we also assess the likelihood of the vesting conditions occurring and apply an appropriate factor in recognizing the expense.

The table below summarizes the stock-based compensation expense included in our statements of operations for the periods indicated (in thousands):

	Year Ended December 31,			Period from May 26, 2004 (Inception) through December 31, 2009
	2009	2008	2007	
Research and development	$2,577	$1,967	$1,243	$ 6,348
Sales and marketing	502	61	33	597
General and administrative	4,676	3,910	3,064	13,223
Stock-based compensation expense included in operating expenses	7,755	5,938	4,340	20,168
Total stock-based compensation expense included in loss from operations	$7,755	$5,938	$4,340	$ 20,168

Long-Lived Assets

We evaluate long-lived assets for impairment of their carrying value when events or circumstances indicate that the carrying value may not be recoverable. Factors we consider in deciding when to perform an impairment review include significant negative industry or economic trends, significant changes or planned changes in our use of the assets, technological obsolescence, or other changes in circumstances which indicate the carrying value of the assets may not be recoverable. If such an event occurs, we evaluate whether the sum of the estimated undiscounted cash flows attributable to the assets in question is less than their carrying value. If this is the case, we recognize an impairment loss to the extent that carrying value exceeds fair value. Fair value is determined based on market prices or discounted cash flow analysis, depending on the nature of the asset and the availability of market data. Any estimate of future cash flows is inherently uncertain. The factors we take into consideration in making estimates of future cash flows include product life cycles, pricing trends, future capital needs, cost trends, product development costs, competitive factors and technology trends as they each affect cash inflows and outflows. If an asset is written down to fair value, that value becomes the asset's new carrying value and is depreciated over the remaining useful life of the asset.

As the result of the discontinuation of our omiganan pentahydrochloride program, we recorded an impairment charge of $2.4 million on our omiganan pentahydrochloride manufacturing equipment during the fourth quarter of 2008. In 2009, we recorded adjustments to this impairment charge, reducing the charge by $0.2 million as actual costs incurred in disposing of the assets were less than anticipated. No similar impairments were recorded for 2007.

Results of Operations

Years ended December 31, 2009 and 2008

Operating Expenses

Research and Development Expenses. Research and development expenses decreased $20.5 million in 2009 to $19.5 million, as compared to $40.0 million for 2008. This reduction was primarily due to a $13.1 million decrease in spending on our omiganan pentahydrochloride product candidate as we discontinued our development efforts for this product candidate in March 2009 following the results of our Phase III clinical trial for this drug. Additionally, research and development spending on our Ofirmev product candidate decreased $8.2 million in 2009 as compared to 2008 as we completed the clinical development program for our Ofirmev NDA and filed it with the FDA in May 2009. Partially offsetting these decreases was an increase in the supporting costs for these programs, including research and development personnel and facility-related costs. More specifically, as compared to 2008, these other supporting costs increased $0.8 million in 2009 to $10.8 million, which was primarily related to additional salary and related personnel costs, including an additional $0.6 million in stock-based compensation charges from additional equity awards outstanding during the 2009 period as compared to the same period in 2008.

Sales and Marketing Expenses. Marketing expenses increased $8.7 million in 2009 to $11.7 million, compared to $3.0 million for 2008. This increase was primarily due to the development of our commercial and supply operations functions for Ofirmev during 2009 as we established our commercial infrastructure in preparation for the potential commercial launch of the product. As part of our development, we increased our sales and marketing staff from two at the end of 2008 to 40 at the end of 2009. Moreover, we incurred additional advertising and promotion costs, outside service fees, market research costs and supported additional grants and continuing medical education in 2009 as compared to 2008.

General and Administrative Expenses. General and administrative expenses increased $1.8 million in 2009 to $12.9 million, compared to $11.1 million for 2008. This increase was primarily due to increases in salaries and related personnel costs, including an additional $0.8 million in stock-based compensation charges from additional equity awards outstanding in 2009 as compared to 2008. Additionally, we incurred additional legal expenses and costs to enhance our information technology infrastructure in 2009 as compared to 2008 as we prepare for the potential commercialization of our Ofirmev product.

Other Expenses. During 2009, we recorded restructuring charges of $0.6 million related to the discontinuation of our omiganan pentahydrochloride development plan. These charges include severance costs associated with a reduction in force of 11 employees and other costs associated with the termination of contractual obligations related to the omiganan pentahydrochloride program. In the fourth quarter of 2008, we recorded an impairment charge of $2.4 million on our omiganan pentahydrochloride manufacturing equipment due to the discontinuance of the program. In 2009 we recorded an adjustment to this impairment, reducing the charge by $0.2 million as the actual costs to dispose of a portion of these assets has been less than anticipated.

Other Income and Expenses, Net

Net other expense increased $0.4 million to $1.0 million in 2009, compared to $0.6 million in 2008. This increase in expense was primarily due to a decrease in the interest income we earned on our investments during 2009 as compared to 2008. For example, in 2009 our interest income was $0.2 million, a decrease of $1.3 million from the $1.5 million earned in 2008. This decrease was due to a lower average yield earned on our investments during 2009 as compared to 2008. Partially offsetting this reduction in interest income is a decrease in the interest expense we incurred on our outstanding debt and a reduction in impairments taken on our equity investment. More specifically, our interest expense decreased $0.8 million in 2009 to $1.1 million, from $1.9 million in 2008, as we made principal payments on our debt arrangements of $7.7 million, reducing the net balance of our debt to $6.4 million at December 31, 2009.

Years ended December 31, 2008 and 2007

Operating Expenses

Research and Development Expenses. Research and development expenses decreased $1.8 million in 2008 to $40.0 million, compared to $41.8 million for 2007. More specifically, the decrease was comprised of the following changes in our programs:

- a decrease of $5.4 million in spending for our omiganan pentahydrochloride development program, primarily due to a reduction in clinical trial activity as enrollment was completed in our Phase III clinical trial in April 2008, partially offset by an increase in pre-commercialization manufacturing development activities;
- an increase of $2.5 million in other supporting costs (including $0.7 million of additional stock-based compensation charges), primarily related to additional salary and related personnel costs resulting from the increase in research and development staff employed during 2008 as compared to 2007, combined with severance costs associated with the departure of an officer during the third quarter of 2008; and
- an increase of $1.1 million in research and development expenses for our Ofirmev program, primarily as a result of increased clinical trial activity during 2008 as compared to 2007, combined with increased costs related to preparations for our NDA filing. The increase in costs for this program was partially offset by facility improvement charges at our manufacturing site incurred primarily in 2007.

Sales and Marketing Expenses. Marketing expenses increased $0.1 million in 2008 to $3.0 million, compared to $2.9 million for 2007. This slight increase was primarily due to increased salaries and related personnel costs from the addition of marketing staff in 2008 as compared to 2007.

General and Administrative Expenses. General and administrative expenses increased $1.5 million in 2008 to $11.1 million, compared to $9.6 million for 2007. This increase was primarily due to an increase of $0.8 million in stock-based compensation charges and increases in salaries and related personnel costs from the addition of general and administrative staff in 2008 as compared to 2007. This increase was partially offset by a reduction in costs associated with outside services during 2008 as compared to 2007.

Other Expenses. During the fourth quarter of 2008, we recorded an impairment charge of $2.4 million on our omiganan pentahydrochloride manufacturing equipment due to the discontinuance of our omiganan pentahydrochloride program. There were no similar charges during 2007.

Other Income and Expenses, Net

Interest income decreased $1.9 million in 2008 to $1.5 million, compared to $3.4 million for 2007. This decrease was primarily due to a lower average yield earned on our investments during 2008 as compared to 2007. Interest expense increased $1.0 million in 2008 to $1.9 million, from $0.9 million in 2007. This increase is due to an amendment to our loan and security agreement under which we secured an additional $15.0 million in December 2007, made to us in two separate draws of $5.0 million and $10.0 million with fixed interest rates of 7.83% and 7.74%, respectively. Partially offsetting the additional interest expense incurred on the $15.0 million draw is a reduction in the interest expense incurred on our $7.0 million loan, drawn in June 2006 at a fixed rate of 11.47%, as a result of principal payments we have been making since February 2007. During the fourth quarter of 2008, we permanently impaired our Migenix holdings by $0.2 million to reduce the carrying value to its current fair value. This impairment charge is included in “Other” expense for 2008. No similar charges were incurred in 2007.

Liquidity and Capital Resources

As a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary pharmaceutical product candidates, we enter into license agreements to acquire the rights to develop and commercialize product candidates. We obtained the exclusive patent rights and know-how for Ofirmev, currently our only product candidate, for the U.S. and Canada pursuant to our license agreement with BMS. Under this agreement, we paid to BMS a $25.0 million up-front fee and may be required to make future milestone payments totaling up to $40.0 million upon the achievement of various milestones related to regulatory and commercial events, including payments totaling $15.0 million upon the approval of our NDA for Ofirmev. In addition, we are also obligated to pay royalties on any net sales of the licensed product.

We had also previously entered into a license agreement for our former omiganan pentahydrochloride product candidate, under which we paid to Migenix an aggregate of $2.0 million in the form of an up-front fee, including the purchase of 617,284 shares of Migenix common stock. In May 2009, we terminated our license agreement with Migenix, and we will not be required to make future milestone or royalty payments under this agreement.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include, but are not limited to, the following:

- the potential for delays in our efforts to seek regulatory approval for Ofirmev, and any costs associated with delays;
- the costs of establishing a commercial organization to sell, market and distribute Ofirmev;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of Ofirmev from our contract manufacturers in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;

- if Ofirmev is approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of intravenous acetaminophen; and
- the success of the commercialization of Ofirmev.

As of December 31, 2009, we had $75.9 million in cash and cash equivalents, an increase of $28.3 million from the $47.6 million at December 31, 2008. This increase was primarily due to proceeds, net of offering costs, received from our private placement completed in February 2009 of approximately $86.2 million, partially offset by cash used in operations ($42.0 million), principal payments on our debt obligations ($7.7 million), net purchases of available-for-sale investment securities ($6.2 million) and purchases of property and equipment ($3.3 million).

The $42.0 million of cash used in operations for 2009 represents a $7.7 million decrease from the $49.7 million of cash used in operations during 2008. The decrease in our use of cash during the 2009 period was primarily due to a reduction in the net loss reported for 2009 compared to 2008 as we discontinued our omiganan development program in March and completed our clinical development program for Ofirmev and submitted our NDA for this product in May. Partially offsetting the reduction in the use of cash from these events, was an increase in sales and marketing expenses as we began establishing our commercial and supply operation functions during the year in preparation for the potential commercial launch of Ofirmev.

The principal payments of $7.7 million made in 2009 reduced our net current and long-term debt balance to $6.4 million at December 31, 2009. The decrease in our net debt balance from the principal payments was partially offset by $0.3 million, related to the amortization of warrant costs issued in connection with the loan agreements and the accrual of the term loan final payment on our $15.0 million credit facility. As of December 31, 2009, we had 12 equal monthly payments remaining on our debt, along with the term loan final payment.

Our net property and equipment balance increased $3.8 million during 2009, to $8.3 million at December 31, 2009. This increase was due to $4.3 million of capital equipment expenditures to be used primarily for the commercial manufacturing of Ofirmev, of which $1.1 million had not been paid for as of December 31, 2009 and was accounted for in accounts payable and accrued expenses. Partially offsetting the equipment purchases in 2009 was depreciation of $0.5 million on our assets that were in service during the year.

Our net accounts payable and accrued liabilities balances decreased $3.5 million, to $10.4 million at December 31, 2009, from $13.9 million at December 31, 2008. This reduction was primarily due to our reduced operating expenses.

Sources of Liquidity

Since inception, our operations have been financed primarily through the issuance of equity securities, in both public and private offerings. From our inception through December 31, 2009, we have received net proceeds of approximately $271.0 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Through December 31, 2009, the sales of shares of our preferred stock, common stock and warrants were as follows:

- from July 2004 to December 2009 (excluding our initial public offering, our February 2008 registered direct offering and our February 2009 private placement), we issued and sold a total of 2,333,803 shares of common stock to our founders, employees, directors and consultants for aggregate net proceeds of $0.9 million;
- from July 2004 to August 2004, we issued and sold a total of 8,085,108 shares of Series A-1 preferred stock for aggregate net proceeds of $7.5 million;

- from June 2005 to September 2005, we issued and sold a total of 17,675,347 shares of Series A-2 preferred stock for aggregate net proceeds of $17.6 million;
- in March 2006, we issued and sold a total of 53,870,000 shares of Series A-3 preferred stock for aggregate net proceeds of $53.8 million;
- in the fourth quarter of 2006, we completed our initial public offering in which we issued and sold a total of 6,900,000 shares of our common stock for aggregate net proceeds of $55.9 million;
- in February 2008, we completed a registered direct offering pursuant to an effective shelf registration in which we issued and sold a total of 9,240,307 shares of our common stock for aggregate net proceeds of $49.1 million; and
- in February 2009, we raised aggregate net proceeds of approximately $86.2 million through a private placement transaction in which we issued 12,039,794 shares of common stock and warrants to purchase up to 6,019,897 additional shares of common stock.

Additionally, in February 2006, we entered into a $7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation to provide us with growth capital. We drew down $7.0 million in June 2006 and in July 2009 we made the final payment to retire the $7.0 million obligation. In November 2007, we amended the $7.0 million loan and security agreement and entered into the Second Amendment to Loan and Security Agreement with the same parties and GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services, Inc.), to secure an additional $15.0 million credit facility. In December 2007, we drew down $15.0 million under the Second Amendment in two separate draws of $5.0 million and $10.0 million with fixed interest rates of 7.83% and 7.74%, respectively, net of a loan fee of less than $0.1 million. In February 2007, we began making the first of 30 equal monthly principal and interest payments on the $7.0 million loan and in July 2008 we began making the first of 30 equal monthly principal and interest payments to fully amortize the balance on the $15.0 million credit facility. As of December 31, 2009, we had no further credit available under these agreements. In connection with each credit facility, we issued warrants to the lenders to purchase shares of our stock.

Capital Resources

Our cash, cash equivalent and short-term investment balances are our primary source of liquidity and will continue to be our only source until we are able to obtain approval and successfully commercialize Ofirmev. We believe we have sufficient financial resources to fund our operations through the next twelve months, including our requirements for projected working capital, capital expenditures and debt servicing. However, we may not have sufficient financial resources to meet all of our objectives once approval is obtained, which could require us to postpone, scale back or eliminate some, or all, of these objectives, including our potential launch activities. Our future funding requirements will depend on many factors, including, but not limited to costs associated with our efforts to:

- obtain regulatory approval for Ofirmev, or any other product candidates that we may license or acquire;
- manufacture commercial quantities of Ofirmev, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell Ofirmev, if it is approved.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with our available financial resources, generated from the proceeds of offerings of our equity securities and our existing borrowings under our amended loan and security agreement. These financial resources may not be adequate to sustain our operations until we are able to generate significant positive cash from operations and we may be required to finance future cash needs through the sale of additional equity securities, strategic collaboration agreements and debt financing. However, we have drawn down all available amounts under our existing amended loan and security agreement, and we may not be successful in obtaining strategic collaboration agreements. Further, we cannot be certain that additional financing will be available when needed or that, if

available, financing will be obtained on terms favorable to us or our stockholders. The capital markets have experienced volatility in recent years and the availability of credit has been adversely affected by illiquid credit markets and wide credit spreads. Further, concern about the stability of the markets in general, and the strength of counterparties specifically, has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may adversely affect our ability to obtain additional financing on terms acceptable to us, or at all. If these market conditions continue, they may limit our ability to timely replace maturing liabilities and to access the capital markets to meet liquidity needs. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our development programs or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. Additionally, if we raise funds by issuing equity securities, dilution to existing stockholders would result; and if we raise funds by incurring additional debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

We have invested a substantial portion of our available cash in money market funds placed with reputable financial institutions and debt instruments of agencies of the U.S. government for which credit loss is not anticipated. The capital markets have been highly volatile and there has been a lack of liquidity for certain financial instruments, especially those with exposure to mortgage-backed securities and auction rate securities. This lack of liquidity has made it difficult for the fair value of these types of instruments to be determined. As of December 31, 2009 our money market fund holdings were invested solely in U.S. government agency securities and U.S. treasuries where an actively traded market is observed and through which values are determined. These funds do not hold auction rate securities.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2009.

Other Significant Cash and Contractual Obligations

The following table summarizes our scheduled contractual obligations and commitments that will affect our future liquidity as of December 31, 2009 (in thousands):

		Payments By Period			
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-term debt obligations, including interest	$ 6,996	$ 6,996	$ —	$ —	$ —
Operating leases[1]	3,334	1,181	2,153	—	—
Process development and facility upgrades[2]	4,596	4,596	—	—	—
License obligations[3]	—	—	—	—	—
Total[4]	$14,926	$12,773	$ 2,153	$ —	$ —

(1) The amounts presented represent commitments for minimum lease payments related to leases of office space and certain equipment under non-cancelable operating leases.

(2) The amounts presented represents our commitments for manufacturing development activities related to our development and supply agreement with Baxter and the purchase of additional manufacturing equipment. In addition, we are required to reimburse Baxter for all reasonable costs for de-installation of our equipment and the restoration of Baxter's manufacturing facility to its pre-installation condition. However, we are not able to reasonably estimate the cost and timing of these expenses at this time and therefore cannot reasonably estimate the fair value of this retirement obligation. As such, we have not included these costs in the amounts presented.

(3) Under our license agreement with BMS, we may be required to make additional future payments of up to $40.0 million, due upon the occurrence of certain milestones related to regulatory or commercial events. We

are also required to pay royalties on any net sales of Ofirmev under the agreement. License payments may be increased based on the timing of various milestones and the extent to which the licensed technologies are pursued for other indications. These milestone payments and royalty payments under our license agreements are not included in the table above because at this time we cannot determine when, or if, the related milestones will be achieved or the events triggering the commencement of payment obligations will occur.

(4) We also enter into agreements with third parties to manufacture our product candidates, conduct our clinical trials and perform data collection and analysis. Our payment obligations under these agreements depend upon the progress of our development programs. Therefore, we are unable at this time to estimate with certainty the future costs we will incur under these agreements. In addition, we enter into unconditional purchase obligations with various vendors and suppliers of goods and services in the normal course of operations through purchase orders or other documentation, or that are undocumented except for an invoice. Such unconditional purchase obligations are generally outstanding for periods less than a year and are settled by cash payments upon delivery of goods and services and are not reflected in this line item.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

Cash Equivalents and Investments

Our cash equivalents and short-term investments are classified as available-for-sale and consisted of money market funds and debt instruments of agencies of the U.S. government at December 31, 2009. The investments in these financial instruments are made in accordance with an investment policy approved by our board of directors which specifies the categories, allocations, and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments that we invest in could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio which may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations would be materially impacted by an immediate change of 10% in interest rates.

We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash, cash equivalents and investment securities have significant risk of default or illiquidity. We made this determination based on discussions with our investment advisors and a review of our holdings. While we believe our cash, cash equivalents and investment securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. All of our investments are held at fair value. The following table shows the fair value of our cash equivalents and investments as of December 31, 2009 (in thousands):

	Amortized Cost Basis	Fair Value
Cash equivalents	$ 73,260	$ 73,260
Available-for-sale debt instruments—U.S. Government agencies (including unrealized gains of less than $1)	6,147	6,147

Debt

The loans under our amended loan and security agreement have fixed interest rates. Consequently, we do not have significant interest rate cash flow exposure on our debt. The aggregate balance of the loans, net of the loan discount, under the agreement at December 31, 2009 was $6.4 million, and is collateralized by substantially all of our assets (excluding intellectual property). Under the terms of the agreement, we are precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and are subject to various non-financial covenants and prepayment penalties.

Item 8. ***Financial Statements and Supplementary Data***

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and
Stockholders of Cadence Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of Cadence Pharmaceuticals, Inc. (a development stage company) as of December 31, 2009 and 2008, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009 and for the period from May 26, 2004 (Inception) through December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits 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 about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cadence Pharmaceuticals, Inc. at December 31, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 and for the period from May 26, 2004 (Inception) through December 31, 2009, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Cadence Pharmaceutical Inc.'s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 15, 2010

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

BALANCE SHEETS

	December 31, 2009	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 75,859,035	$ 47,627,246
Investments in marketable securities	6,147,118	—
Restricted cash	1,497,848	2,195,696
Prepaid expenses	517,987	144,118
Other current assets	31,256	75,556
Total current assets	84,053,244	50,042,616
Property and equipment, net	8,300,529	4,477,020
Restricted cash	189,738	537,586
Other assets	19,708	90,792
Total assets	$ 92,563,219	$ 55,148,014
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,656,597	$ 4,877,854
Accrued liabilities	7,739,527	9,063,310
Current portion of long-term debt, less discount of $158,545 and $218,851, respectively	6,442,327	7,694,173
Other current liabilities	22,048	22,048
Total current liabilities	16,860,499	21,657,385
Deferred rent	640,208	952,274
Long-term debt, less current portion and discount of $-0- and $158,545, respectively	—	6,098,113
Total liabilities	17,500,707	28,707,772
Commitments and contingencies (Note 7)		
Stockholders' equity :		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2009 and 2008, respectively	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized, 50,484,588 shares and 38,363,985 shares issued and outstanding at December 31, 2009 and 2008, respectively	5,048	3,836
Additional paid-in capital	292,076,537	197,964,600
Accumulated other comprehensive income	60	—
Deficit accumulated during the development stage	(217,019,133)	(171,528,194)
Total stockholders' equity	75,062,512	26,440,242
Total liabilities and stockholders' equity	$ 92,563,219	$ 55,148,014

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF OPERATIONS

	Year Ended December 31,			Period from May 26, 2004 (Inception) through December 31, 2009
	2009	2008	2007	
Operating expenses:				
Research and development	$ 19,464,200	$ 40,018,204	$ 41,781,357	$ 157,100,105
Sales and marketing	11,729,102	2,983,796	2,865,804	18,670,492
General and administrative	12,890,990	11,146,212	9,586,705	40,858,984
Other	412,341	2,384,251	—	2,796,592
Total operating expenses	44,496,633	56,532,463	54,233,866	219,426,173
Loss from operations	(44,496,633)	(56,532,463)	(54,233,866)	(219,426,173)
Other (expense) income:				
Interest income	181,710	1,530,172	3,404,447	7,326,402
Interest expense	(1,137,398)	(1,916,315)	(867,524)	(4,418,854)
Other expense	(38,618)	(180,244)	(16,611)	(500,508)
Total other (expense) income, net	(994,306)	(566,387)	2,520,312	2,407,040
Loss before income tax	(45,490,939)	(57,098,850)	(51,713,554)	(217,019,133)
Net loss	$ (45,490,939)	$ (57,098,850)	$ (51,713,554)	$ (217,019,133)
Basic and diluted net loss per share[1]	$ (0.93)	$ (1.55)	$ (1.81)	
Shares used to compute basic and diluted net loss per share[1]	48,753,978	36,823,660	28,572,833	

(1) As a result of the issuance of 12,039,794 shares of common stock pursuant to a private placement in the first quarter of 2009 and 9,240,307 shares of common stock pursuant to an effective shelf registration in the first quarter of 2008, there is a lack of comparability in the per share amounts between the periods presented. Please see Note 2 of the Notes to Financial Statements for further discussion.

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY

	Series A-1 to A-3 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount					
Issuance of common stock to founders in July at $0.004 per share	—	$ —	1,125,000	$ 112	$ 4,388	$ —	$ —	$ 4,500	
Issuance of Series A-1 preferred stock, net of $59,573 offering costs in December at $0.94 per share	8,085,108	809	—	—	7,539,620	—	—	7,540,429	
Issuance of common stock from option exercises under equity compensation plans	—	—	45,000	5	17,995	—	—	18,000	
Issuance of common stock options for consulting services in November	—	—	—	—	811	—	—	811	
Net Loss	—	—	—	—	—	—	(2,837,237)	(2,837,237)	$ (2,837,237)
Balance at December 31, 2004	**8,085,108**	**809**	**1,170,000**	**117**	**7,562,814**	**—**	**(2,837,237)**	**4,726,503**	**$ (2,837,237)**
Issuance of Series A-2 preferred stock, net of $57,041 offering costs in June and September at $1.00 per share	17,675,347	1,767	—	—	17,616,539	—	—	17,618,306	
Issuance of common stock from option exercises under equity compensation plans, net of repurchase of shares from option exercises	—	—	734,000	73	105,927	—	—	106,000	
Net Loss	—	—	—	—	—	—	(7,705,612)	(7,705,612)	$ (7,705,612)
Balance at December 31, 2005	**25,760,455**	**2,576**	**1,904,000**	**190**	**25,285,280**	**—**	**(10,542,849)**	**14,745,197**	**$ (7,705,612)**
Issuance of Series A-3 preferred stock, net of $94,987 offering costs in March at $1.00 per share	53,870,000	5,387	—	—	53,769,626	—	—	53,775,013	
Conversion of preferred stock in connection with initial public offering in October	(79,630,455)	(7,963)	19,907,605	1,990	5,973	—	—	—	
Initial public offering of common stock, net of $6,204,852 offering costs, in October at $9.00 per share	—	—	6,900,000	690	55,894,458	—	—	55,895,148	
Issuance of warrants in February to purchase 385,000 shares of common stock at $1.00 per share	—	—	—	—	313,572	—	—	313,572	
Cashless warrant exercise in November at $9.45 per shares	—	—	27,754	3	(3)	—	—	—	
Issuance of common stock from option exercises under equity compensation plans	—	—	353,361	36	466,426	—	—	466,462	
Collection of stock subscription receivable	—	—	—	—	187,600	—	—	187,600	
Stock-based compensation	—	—	—	—	2,134,958	—	—	2,134,958	
Unrealized gain on investment securities	—	—	—	—	—	64,033	—	64,033	$ 64,033
Net Loss	—	—	—	—	—	—	(52,172,941)	(52,172,941)	(52,172,941)
Balance at December 31, 2006	**—**	**—**	**29,092,720**	**2,909**	**138,057,890**	**64,033**	**(62,715,790)**	**75,409,042**	**$ (52,108,908)**

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY—Continued

	Series A-1 to A-3 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount					
Issuance of warrants in November to purchase 50,331 shares of common stock at $12.67 per share	—	—	—	—	473,876	—	—	473,876	
Cashless warrant exercise in March at $15.04 per share	—	—	35,325	4	(4)	—	—	—	
Net repurchase of common stock from option repurchases under equity compensation plans	—	—	(15,290)	(2)	7,912	—	—	7,910	
Stock-based compensation	—	—	—	—	4,340,305	—	—	4,340,305	
Unrealized loss on investment securities	—	—	—	—	—	(59,509)	—	(59,509)	$ (59,509)
Net Loss	—	—	—	—	—	—	(51,713,554)	(51,713,554)	(51,713,554)
Balance at December 31, 2007	**—**	**—**	**29,112,755**	**2,911**	**142,879,979**	**4,524**	**(114,429,344)**	**28,458,070**	**$ (51,773,063)**
Registered direct offering of common stock, net of $204,222 offering costs, in February at $5.34 per share	—	—	9,240,307	924	49,138,093	—	—	49,139,017	
Issuance of common stock from option exercises under equity compensation plans	—	—	10,923	1	8,929	—	—	8,930	
Stock-based compensation	—	—	—	—	5,937,599	—	—	5,937,599	
Unrealized loss on investment securities	—	—	—	—	—	(4,524)	—	(4,524)	$ (4,524)
Net Loss	—	—	—	—	—	—	(57,098,850)	(57,098,850)	(57,098,850)
Balance at December 31, 2008	**—**	**—**	**38,363,985**	**3,836**	**197,964,600**	**—**	**(171,528,194)**	**26,440,242**	**$ (57,103,374)**
Private placement offering of common stock, net of $353,498 offering costs, in February at $7.13 per share and warrants to purchase 6,019,897 shares of common stock at $7.84 for $0.125	—	—	12,039,794	1,204	86,241,516	—	—	86,242,720	
Issuance of common stock from option exercises under equity compensation plans	—	—	80,809	8	115,244	—	—	115,252	
Stock-based compensation	—	—	—	—	7,755,177	—	—	7,755,177	
Unrealized gain on investment securities	—	—	—	—	—	60	—	60	$ 60
Net Loss	—	—	—	—	—	—	(45,490,939)	(45,490,939)	(45,490,939)
Balance at December 31, 2009	**—**	**$ —**	**50,484,588**	**$ 5,048**	**$292,076,537**	**$ 60**	**$(217,019,133)**	**$ 75,062,512**	**$ (45,490,879)**

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF CASH FLOWS

	Year Ended December 31,			Period from May 26, 2004 (Inception) through December 31, 2009
	2009	2008	2007	
Operating activities				
Net loss	$(45,490,939)	$(57,098,850)	$(51,713,554)	$ (217,019,133)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	537,359	529,646	515,763	1,849,714
Loss on disposal of assets	6,699	31,089	—	74,822
Impairment of long-lived assets	—	2,353,162	—	2,353,162
Adjustment to estimate of impairment of long-lived assets	(180,926)	—	—	(180,926)
Impairment of available-for-sale securities	45,461	176,539	—	450,000
Stock-based compensation	7,755,177	5,937,599	4,340,305	20,168,850
Non-cash interest expense	25,623	31,108	8,622	72,889
Amortization of discount on note payable	218,851	264,734	106,190	673,902
Accretion of premiums on available-for-sale securities, net of accretion of discounts	130,269	—	—	130,269
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(443,548)	689,647	(153,505)	(755,817)
Accounts payable	(1,930,454)	3,017,446	(98,735)	2,791,328
Accrued liabilities and other liabilities	(2,721,345)	(5,619,868)	6,320,244	5,619,542
Net cash used in operating activities	(42,047,773)	(49,687,748)	(40,674,670)	(183,771,398)
Investing activities				
Purchases of marketable securities	(10,738,348)	—	—	(18,188,348)
Maturities of marketable securities	4,575,000	—	—	11,575,000
Restricted cash	1,045,696	134,000	(1,286,152)	(1,687,586)
Purchases of property and equipment	(3,266,948)	(1,742,761)	(2,096,683)	(9,778,460)
Proceeds from the sale of property and equipment	—	195	—	195
Net cash used in investing activities	(8,384,600)	(1,608,566)	(3,382,835)	(18,079,199)
Financing activities				
Proceeds from issuance of common stock	86,357,972	49,147,947	23,985	192,489,087
Disbursements from repurchase of common stock	—	—	(16,075)	(19,075)
Proceeds from sale of preferred stock, net	—	—	—	78,933,748
Borrowings under debt agreements	—	—	14,955,000	21,955,000
Principal payments under debt agreements	(7,693,810)	(5,617,308)	(2,338,010)	(15,649,128)
Net cash provided by financing activities	78,664,162	43,530,639	12,624,900	277,709,632
Net increase (decrease) in cash and cash equivalents	28,231,789	(7,765,675)	(31,432,605)	75,859,035
Cash and cash equivalents at beginning of period	47,627,246	55,392,921	86,825,526	—
Cash and cash equivalents at end of period	$ 75,859,035	$ 47,627,246	$ 55,392,921	$ 75,859,035
Supplemental disclosures				
Issuance of warrants in connection with loan and security agreement	$ —	$ —	$ 473,876	$ 787,448
Assets acquired through lease concessions	$ —	$ —	$ —	$ 1,190,530
Property and equipment purchases in accounts payable and accrued expenses	$ 1,100,621	$ —	$ —	$ 1,100,621
Unrealized gain (loss) on investment securities	$ 60	$ (4,524)	$ (59,509)	$ 60
Cash paid for interest and fees	$ 814,452	$ 1,483,420	$ 693,288	$ 3,330,162

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS

1. The Company

Cadence Pharmaceuticals, Inc. (the "Company") was incorporated in the state of Delaware in May 2004. The Company is a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. The Company's primary activities since incorporation have been conducting research and development activities, including clinical trials, of the product candidates in its portfolio; organizational activities, including recruiting personnel, establishing office facilities; establishing the commercial manufacturing and sales infrastructure for its Ofirmev™ product; and raising capital to fund these activities. To date, the Company has in-licensed rights to two late-state product candidates, Ofirmev™, an intravenous formulation of acetaminophen, and omiganan pentahydrochloride 1% aqueous gel. In May 2009, the Company submitted a New Drug Application ("NDA"), for Ofirmev to the Food and Drug Administration ("FDA"). On February 10, 2010, the Company received a complete response letter from the FDA, which stated the NDA could not be approved due to deficiencies observed during the FDA's inspection of the facilities of the Company's third-party manufacturer. The Company's third-party manufacturer received a related letter detailing the observations, and on February 18, 2010 the third-party manufacturer submitted a response letter to the FDA responding to these observations.

In March 2009, the Company announced that its Phase III clinical trial of omiganan pentahydrochloride did not meet its primary endpoint, and that it was discontinuing its development efforts for this product candidate because the results would not support an NDA submission. At the same time, the Company implemented cost reduction measures and restructured its operations to make additional resources available for its Ofirmev program and other operating activities. Since the Company has not begun principal operations of commercializing Ofirmev, the Company is considered to be a development stage company.

2. Summary of Significant Accounting Policies

Management Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. On a regular basis, the Company reviews its estimates to ensure the estimates appropriately reflect changes in its business or as new information becomes available. Management believes that these estimates are reasonable; however, actual results could materially differ from these estimates.

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, restricted cash, accounts payable, accrued liabilities and long-term debt. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, restricted cash, accounts payable and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The fair value of marketable securities is based upon market prices quoted on the last day of the fiscal period.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

Effective January 1, 2008, the Company adopted new authoritative guidance for fair value measurements. This new guidance defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements, but does not require any new fair value measurements. The valuation techniques included in the guidance are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect market assumptions and are classified into the following fair value hierarchy:

Level 1 Inputs – Quoted prices for identical instruments in active markets.

Level 2 Inputs – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable.

Level 3 Inputs – Valuation derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Currently, all of the Company's financial instruments are valued using level 1 inputs. The following table presents further detail of the financial instruments carried at fair value on the Company's balance sheet as of December 31, 2009. The table does not include assets and liabilities which are measured at historical cost or on any basis other than fair value:

Description	Total Carrying Value	Fair Value Measurements as of December 31, 2009			
		Level 1	Level 2	Level 3	Total Fair Value
Assets:					
Cash and cash equivalents:					
Money market funds	$ 73,260,312	$ 73,260,312	$ —	$ —	$ 73,260,312
Investments in marketable securities—short-term:					
Debt instruments—U.S. Government agencies	6,147,118	6,147,118	—	—	6,147,118
Assets at fair value	$ 79,407,430	$ 79,407,430	$ —	$ —	$ 79,407,430

Cash Equivalents

The Company considers all highly liquid investments purchased with maturities of three months or less to be cash equivalents. These investments may include money market funds, U.S. Government agencies, corporate debt securities and commercial paper. As of December 31, 2009 and 2008, the Company's cash equivalents were $73,260,312 and $47,331,056, respectively.

Marketable Securities

The Company determines the appropriate classification of its investments at the time of acquisition and reevaluates such determination at each balance sheet date. The Company's investment policy set minimum credit quality criteria and maximum maturity limits on its investments to provide for safety of principle, liquidity and a reasonable rate of return. Investments for which maturity from the balance sheet date is greater than one year are classified as long-term investments in marketable securities. Available-for-sale securities are recorded at fair value, based on current market valuations. Unrealized holding gains and losses on available-for-sale securities

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

are excluded from earnings and are reported as a separate component of other comprehensive income until realized. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of the securities sold.

The Company has classified its investment holdings as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies. During the years ended December 31, 2009 and 2008, the Company recorded an impairment charge to reduce the value of an available-for-sale equity security by $45,461 and $176,539, respectively, as the market value was significantly below the security's carrying value. See Note 3 for further discussion.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash, cash equivalents, restricted cash and marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. However, management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain safety and liquidity.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as principally one segment.

Property and Equipment

Property and equipment, including leasehold improvements, are stated at cost. Rent expense for operating leases is recorded on a straight-line basis over the life of the lease term. If a lease has a fixed and determinable escalation clause, the difference between the rent expense and rent paid is recorded as deferred rent. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which are generally as follows: seven years for manufacturing equipment; five years for furniture and equipment; and three years for computer equipment and software. Leasehold improvements are amortized over the shorter of their useful lives or the terms of the related leases. Asset lives are reviewed periodically to determine if appropriate and adjustments are made as necessary. Depreciation begins at the time the asset is placed in service. Maintenance and repairs are expensed as incurred.

For the years ended December 31, 2009, 2008 and 2007, the Company recorded depreciation expense of $537,359, $529,646 and $515,763, respectively. Since May 26, 2004 (inception) through December 31, 2009, the Company has incurred $1,849,714 of depreciation expense.

Impairment of Long-Lived Assets

Long-lived assets such as property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or the fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposed group classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet.

During the fourth quarter of 2008, the Company recorded an impairment charge of $2,353,162 related to its omiganan pentahydrochloride manufacturing assets due to the discontinuance of the Company's omiganan pentahydrochloride program. During 2009, the Company recorded an adjustment to the impairment charge taken on the manufacturing equipment, reducing the charge by $180,926 as actual costs incurred in disposing of the assets were less than anticipated. No similar impairment or adjustment was recorded for the year ended December 31, 2007.

Research and Development

The Company's research and development expenses consist primarily of license fees, salaries and related employee benefits, costs associated with clinical trials managed by the Company's contract research organizations ("CROs"), and costs associated with non-clinical activities, such as regulatory and pre-commercialization manufacturing expenses. The Company uses external service providers and vendors to conduct clinical trials, to manufacture product candidates to be used in clinical trials and to provide various other research and development related products and services. The Company accounts for research and development expenditures as incurred and accrues expenses based upon estimates of work performed, patient enrollment and experience with similar contracts.

Income Taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. A valuation allowance is recorded when it is more likely than not that some of the deferred tax assets will not be realized. In determining the need for valuation allowances the Company considers projected future taxable income and the availability of tax planning strategies. If in the future the Company determines that it would not be able to realize its recorded deferred tax assets, an increase in the valuation allowance would be recorded, decreasing earnings in the period in which such determination is made.

The Company assesses its income tax positions and record tax benefits for all years subject to examination based upon its evaluation of the facts, circumstances and information available at the reporting date. For those tax positions where there is a greater than 50% likelihood that a tax benefit will be sustained, the Company has recorded the largest amount of tax benefit that may potentially be realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. For those income tax positions where there is less than 50% likelihood that a tax benefit will be sustained, no tax benefit has been recognized in the financial statements.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS—Continued

Stock-Based Compensation

The Company has stock-based compensation plans, which are described in Note 9. As of December 31, 2009, the Company had issued both stock option awards and restricted stock units under its stock-based compensation plans.

Stock option awards. Stock options are currently valued using the Black-Scholes option pricing model on the date of grant. This option pricing model involves a number of estimates, including the expected lives of stock options, the Company's anticipated stock volatility and interest rates. The following table summarizes the average estimates the Company used in the Black-Scholes option pricing model for the years ended December 31, 2009, 2008 and 2007, to determine the fair value of stock options granted during each period:

	Year Ended December 31,		
	2009	2008	2007
Risk free interest rates	2.2%	2.9%	4.6%
Expected life in years	6.0 years	6.0 years	6.0 years
Expected dividend yield	0.0%	0.0%	0.0%
Expected volatility	71.6%	70.0%	66.2%

The Company determines its risk-free interest rate assumption based on the U.S. Treasury yield for obligations with contractual lives similar to the expected lives of the Company's share-based payment awards being valued. The weighted-average expected life of options was calculated using the simplified method, as prescribed by the Securities and Exchange Commission ("SEC"), due to the lack of relevant historical exercise data. The Company anticipates it will continue to use the simplified method until such data is available. In addition, due to the Company's limited historical stock price volatility data, the estimated volatility is calculated by incorporating the historical volatility of comparable companies. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Forfeitures are estimated based upon the historical and anticipated future experience. Based upon these assumptions, the Company has estimated the per share weighted-average grant date fair value of its options granted for the years ended December 31, 2009, 2008 and 2007 at $5.99, $4.13 and $9.53, respectively.

Restricted stock unit awards. Restricted stock units ("RSUs") are valued based on the fair market value of the Company's stock on the date of grant and the Company recognizes expense for RSUs if vesting is considered probable. In August 2009, the Company granted a total of 300,500 RSUs to certain officers and employees. One-half of the RSUs were to vest upon the approval by the FDA of the NDA for Ofirmev, if such approval occurred prior to December 31, 2009. At December 31, 2009, the Company had not received approval of its Ofirmev NDA and therefore the performance criteria for these grants was not achieved. As such, the awards were forfeited and all previously recorded expense associated with these RSUs was recovered. The remaining half of the RSUs are to vest upon the first anniversary of the approval by the FDA of the NDA for Ofirmev, if such approval is received. These RSUs continue to be outstanding as of December 31, 2009.

Compensation expense for all stock-based payment awards is recognized using the straight-line method. Stock-based compensation expense recognized during the period is based on the value of the portion of awards that is ultimately expected to vest. Hence, the gross expense is reduced for estimated forfeitures and adjusted for the probability of achieving performance criteria. More specifically, the performance conditions for the August 2009 RSU grants that remained outstanding at December 31, 2009, were considered probable of being achieved and therefore stock-based compensation expense of $402,372 related to the RSU grants was recognized during 2009. There was no expense recognized for the RSUs that were forfeited during the year as the performance criteria was not achieved.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

The table below summarizes the total stock-based compensation expense included in the Company's statements of operations for the periods presented:

	Year Ended December 31,			Period from May 26, 2004 (Inception) through December 31, 2009
	2009	2008	2007	
Research and development	$ 2,577,501	$ 1,966,977	$ 1,243,173	$ 6,348,908
Sales and marketing	501,780	61,119	32,808	596,878
General and administrative	4,675,896	3,909,503	3,064,324	13,223,064
Stock-based compensation expense included in operating expenses	7,755,177	5,937,599	4,340,305	20,168,850
Total stock-based compensation expense included in loss from operations	$ 7,755,177	$ 5,937,599	$ 4,340,305	$ 20,168,850

As of December 31, 2009, the total future compensation expense related to unvested stock options and RSUs, net of estimated forfeitures, is expected to be approximately $14,982,477. This expense is expected to be recognized over a weighted-average period of approximately 31 months. The total fair value of shares vested during 2009, 2008 and 2007 was $6,545,744, $6,339,912 and $4,602,921, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Components of comprehensive income (loss) include foreign currency translation adjustments and unrealized gains and losses on the changes in fair value of investments. These components are added, net of their related tax effect, to the reported net income (loss) to arrive at comprehensive income (loss).

Net Loss Per Share

Net loss per share is presented as basic and diluted net loss per share. Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options, restricted stock units and warrants are considered to be common stock equivalents and are not included in the calculations of diluted net loss per share as their effect is anti-dilutive. Additionally, the restricted stock units outstanding during 2009 were excluded from the basic net loss calculation as these units do not include dividend rights and therefore are not considered to be participating securities.

The actual net loss per share amounts for the years ended December 31, 2009, 2008 and 2007 were computed based on the weighted average shares of common stock outstanding during the respective periods. The net loss per share for the years presented include the effect of the (i) 12,039,794 common shares issued pursuant to a private placement in the first quarter of 2009 and (ii) 9,240,307 common shares issued pursuant to an effective shelf registration in the first quarter of 2008. As a result of the issuance of these common shares, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

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

	Year Ended December 31,		
	2009	2008	2007
Shares for basic and dilutive net loss per share:			
Weighted average common shares outstanding	48,841,365	37,094,918	29,107,093
Weighted average unvested common shares subject to repurchase	(87,387)	(271,258)	(534,210)
Denominator for basic and diluted earnings per share	48,753,978	36,823,660	28,572,883

At December 31, 2009, 2008 and 2007, options, restricted stock units and warrants totaling 11,445,860, 3,851,451 and 2,900,634 shares, respectively, were excluded from the calculation as their effect would have been anti-dilutive.

Recent Accounting Pronouncements

In May 2009, the Financial Accounting Standards Board (“FASB”) issued guidance regarding subsequent events, which is intended to establish general standards of accounting for, and disclosure of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. Specifically, the guidance sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. In February 2010, the FASB amended the guidance to remove the requirement for management to disclose the date through which the company had evaluated its subsequent events in issued and revised financial statements. The guidance is effective for financial statements issued for interim and annual financial periods ending after June 15, 2009 and the amended guidance is effective February 24, 2010. The Company adopted the provisions of the guidance which did not have a material effect on the Company’s financial statements.

3. Investments in Marketable Securities

In accordance with the Company’s investment policy, it has invested funds in marketable debt securities. Further, the Company acquired 617,284 shares of Migenix common stock as partial consideration from its acquisition of the development and commercialization rights to the Migenix, Inc. (“Migenix”) omiganan pentahydrochloride product candidate in July 2004. Investments are considered to be impaired when a decline in fair value is judged to be other-than-temporary. The Company employs a methodology that reviews specific securities in evaluating potential impairment of its investments. In the event that the cost of an investment exceeds its fair value, the Company evaluates, among other factors, the Company’s intent and ability to hold the investment and extent to which the fair value is less than cost; the financial health of and business outlook for the issuer; and operational and financing cash flow factors.

At the time of acquisition the Migenix stock, these shares were recorded at an initial cost of $450,000 and in 2005 and 2004, the Company recognized non-cash impairment charges on the shares of $183,000 and $45,000, respectively, related to decreases in the market value of the Migenix stock that were considered to be other-than-temporary. In 2008, the Company recorded an additional other-than-temporary impairment charge of $176,539 to further reduce the book value of the Company’s equity security position in its Migenix holding to the current fair

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

value. In 2009, the Company recorded a charge of $45,461 to impair the remaining balance of the security holding after the Company discontinued its omiganan pentahydrochloride program. These charges are included in "Other" non-operating expense on the Company's statement of operations for the years ended December 31, 2009 and 2008, respectively. No similar impairment charges were recorded for the year ended December 31, 2007.

The cost, gross unrealized holding gains, gross unrealized holding losses and fair value of available-for-sale investments by types and classes of security at December 31, 2009 and December 31, 2008 consisted of the following:

At December 31, 2009	Amortized Cost Basis	Other-than-temporary Impairments	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Available-for-sale:					
Debt instruments—U.S. Government agencies	$6,147,058	$ —	$ 786	$ (726)	$6,147,118
	$6,147,058	$ —	$ 786	$ (726)	$6,147,118

At December 31, 2008	Amortized Cost Basis	Other-than-temporary Impairments	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Available-for-sale:					
Equity securities	$ 450,000	$ (404,539)	$ —	$ —	$ 45,461
	$ 450,000	$ (404,539)	$ —	$ —	$ 45,461

Investments by contractual maturity are as follows:

	December 31, 2009		December 31, 2008	
	Cost	Fair Value	Cost	Fair Value
Due or callable in one year or less	$6,147,058	$6,147,118	$—	$ —
Due after one year	$ —	$ —	$—	$ —

CADENCE PHARMACEUTICALS, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS—Continued

4. Selected Financial Statement Data

	As of December 31, 2009	As of December 31, 2008
Property and equipment:		
Leasehold improvements	$ 1,610,250	$ 1,592,404
Computer equipment and software	840,604	607,319
Furniture and fixtures	469,423	427,811
Construction-in-process	7,059,969	3,008,972
	9,980,246	5,636,506
Less accumulated depreciation	(1,679,717)	(1,159,486)
Total	$ 8,300,529	$ 4,477,020
Accrued liabilities:		
Accrued manufacturing costs and equipment purchases	$ 3,361,235	$ 2,124,053
Accrued personnel costs	2,875,607	2,053,087
Accrued clinical research costs	106,283	623,444
Other accrued liabilities	1,396,402	1,873,796
Accrued patient costs	—	2,388,930
Total	$ 7,739,527	$ 9,063,310

5. Omiganan Pentahydrochloride Restructuring and Impairment Charges

In March 2009, the Company announced its decision to discontinue the development of its omiganan pentahydrochloride product candidate. This decision was due to the failure of the Company's Phase III clinical trial of omiganan pentahydrochloride to meet its primary endpoint and the Company's belief that the results of this clinical trial would not support an NDA submission. In connection with the discontinuation of the development of omiganan pentahydrochloride, the Company implemented a corporate restructuring in order to reduce, and eventually eliminate, costs associated with the omiganan pentahydrochloride program, including the termination of 11 employees. The Company recorded impairment charges in the fourth quarter of 2008 of $2,353,162 with respect to certain omiganan pentahydrochloride manufacturing equipment, based upon management estimates of the salvage value of the equipment at the time the impairment charge was taken. Further, the Company recorded restructuring charges of $650,786 in the first quarter of 2009 for severance-related costs and the termination of contractual obligations, based upon management estimates of the termination costs at the time they were recorded. These estimates can change depending upon changes in facts and circumstances subsequent to the date the original liability was recorded.

The Company recorded adjustments to the impairment charge taken on the manufacturing equipment in 2009, reducing the charge by $180,926 as actual costs incurred in disposing of the assets were less than anticipated. Additionally, adjustments totaling $64,219 were recorded to the severance obligation in 2009. All of the charges and adjustments are included in the Company's "Other" operating expenses on the statement of operations. As of December 31, 2009, no liability remained for severance-related costs and termination of contractual obligations. Further, there was no such liability at December 31, 2008.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

The following table details the restructuring charges for severance-related costs and termination of contractual obligations for periods presented:

	Year Ended December 31,			Period from May 26, 2004 (Inception) through December 31, 2009
	2009	2008	2007	
Beginning restructuring liability	$ —	$—	$—	$ —
Severance and termination charges incurred	650,786	—	—	650,786
Adjustments to severance and termination charges	(64,219)	—	—	(64,219)
Severance and termination disbursements	(586,567)	—	—	(586,567)
Ending restructuring liability	$ —	$—	$—	$ —

Further, on May 8, 2009, the Company notified Migenix of the termination of the license agreement for omiganan pentahydrochloride, and informed Solvay, S.A. (“Solvay”) of its intention to terminate the long-term supply agreement and a related license agreement for the active ingredient in omiganan pentahydrochloride. The termination of the long-term supply agreement and related license agreement became effective on July 7, 2009. No charges were incurred from the termination of these agreements.

6. Loan and Security Agreement

In February 2006, the Company entered into a $7,000,000 Loan and Security Agreement (the “Agreement”) with Silicon Valley Bank and Oxford Finance Corporation to provide growth capital to the Company. In June 2006, the Company drew down $7,000,000 under the Agreement at a fixed interest rate of 11.47%. In August 2006, the Company began making the first of six monthly interest-only payments on the $7,000,000 balance and in February 2007, began making equal monthly principal and interest payments. The Company made the final payment to retire the obligation in July 2009.

In November 2007, the Company amended the Agreement and entered into the Second Amendment to Loan and Security Agreement (the “Second Amendment”) with the same parties and GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.), to secure an additional $15,000,000 credit facility. In December 2007, the Company drew down $15,000,000 under the Second Amendment in two separate draws of $5,000,000 and $10,000,000 with fixed interest rates of 7.83% and 7.74%, respectively, net of a $45,000 loan fee (the “loan fee”). In January 2008, the Company began making the first of six monthly interest-only payments on the $15,000,000 balance of the Second Amendment and in July 2008, began making the first of 30 equal monthly principal and interest payments.

In addition to the principal and interest, the Company is required to pay $375,000 at the termination of Second Amendment (the “term loan final payment”). The loan fee and the warrants issued in connection with the loan (as described below), have been recognized as a discount on the loan issuance which, together with the fixed interest rates, will be amortized to interest expense throughout the life of the loan using an effective interest rate of 9.56%. The term loan final payment is being accrued through interest expense over the life of the loan. All interest payable under the Second Amendment and the full amount of the term loan final payment must be paid upon any prepayment of the loan. The loans are collateralized by substantially all the assets of the Company (excluding intellectual property). Under the terms of the Agreement, the Company may be precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and is subject to certain non-financial covenants and prepayment penalties. Upon the occurrence of an event of default, including a Material Adverse Change (as defined in the Agreement), the lenders may declare all outstanding amounts due and payable under the Agreement.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

As of December 31, 2009 and 2008, the aggregate principal balance of the loans, net of the loan discount, included on the Company's balance sheets was $6,442,327 and $13,792,286, respectively.

Warrants

In connection with the Agreement with Silicon Valley Bank and Oxford Finance Corporation, the Company issued two fully exercisable warrants to the lenders to purchase an aggregate of 385,000 shares of the Company's Series A-2 preferred stock at an exercise price of $1.00 per share. These warrants became exercisable for 96,250 shares of the Company's common stock, at an exercise price of $4.00 per share, upon the completion of the Company's initial public offering in October 2006. The $313,572 fair value of the warrants was determined using the Black-Scholes valuation model, recorded as a discount to the note payable, and amortized to interest expense over the term of the loan agreement. The warrants were valued using the following assumptions: risk-free interest rate of 4.57%; dividend yield of 0.0%; expected volatility of 70.0%; and a contractual term of 10 years. In November 2006, one warrant was exercised for 48,125 shares of the Company's common stock at a price of $9.45, resulting in 27,754 shares issued on a net exercise basis. In March 2007, the remaining warrant was exercised for 48,125 shares of the Company's common stock at a price of $15.04, resulting in 35,325 shares issued on a net exercise basis.

In connection with the Second Amendment to the Agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc., the Company issued six fully exercisable warrants to the lenders to purchase an aggregate of 50,331 shares of the Company's common stock at an exercise price of $12.67 per share, expiring November 30, 2014. The Company determined the fair value of these warrants to be $473,876, using the Black-Scholes valuation model. The value of the warrants was recorded as a discount to the note payable, and will be amortized to interest expense over the expected term of the loan agreement. The warrants were valued using the following assumptions: risk-free interest rate of 3.64%; dividend yield of 0.0%; expected volatility of 70.0%; and a contractual term of seven years. As of December 31, 2009, all warrants related to the Second Amendment were outstanding.

7. Commitments and Contingencies

Leases

In May 2006, the Company entered into a six-year operating lease for 23,494 square feet of office space. The Company received certain tenant improvement allowances and rent abatement and has an option to extend the lease for five years following the expiration of the initial term. Monthly rental payments are adjusted on an annual basis and the lease expires in September 2012. As security for the lease, a letter of credit in the initial amount of $1,581,130 was required by the landlord. The letter of credit is collateralized by a certificate of deposit in the same amount that is classified as restricted cash in the Company's balance sheet. The required amount subject to the letter of credit and corresponding certificate of deposit may be reduced by 22% on each of the first four anniversaries of the commencement of the lease. During the fourth quarter of 2007, the first quarter of 2009 and the fourth quarter of 2009, the letter of credit was reduced by $347,848 each in accordance with the agreement and the related restricted cash was adjusted by a like amount. The value of the letter of credit and corresponding certificate of deposit, classified as restricted cash on the Company's balance sheet, as of December 31, 2009 was $537,586.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

In January 2007, the Company entered into a sublease agreement for a portion of its unused office space. The sublease agreement expired during the third quarter of 2009 and the Company has since recaptured the space to support its growth. The Company also leases certain office equipment under operating leases with terms that range from one to four years and expire in 2012. As of December 31, 2009, the total future minimum payments under operating leases, including rent and office equipment, were as follows:

2010	$ 1,181,249
2011	1,218,953
2012	933,552
2013	—
2014	—
Thereafter	—
	$ 3,333,754

Rent expense, net of sublease rent income, for the years ended December 31, 2009, 2008 and 2007 was $653,466, $568,134 and $576,124, respectively. Since May 26, 2004 (inception) through December 31, 2009, the Company has incurred net rent expense of $2,774,706.

Supply Agreements

Baxter Healthcare Corporation

In July 2007, the Company entered into a development and supply agreement (the "Supply Agreement") with Baxter Healthcare Corporation ("Baxter") for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of the finished drug product for Ofirmev. The Supply Agreement has an initial term of five years and will automatically renew for consecutive one-year terms thereafter unless either party provides at least two-years' prior written notice of termination to the other party. Pursuant to the terms of the Supply Agreement, Baxter is entitled to receive development fees from the Company upon the completion of specified development activities, which the Company expenses as these costs are being incurred. In addition, Baxter will receive a set manufacturing fee based on the amount of the finished Ofirmev drug product produced, which prices may be adjusted by Baxter, subject to specified limitations. The Company is also obligated to purchase a minimum number of units each year following regulatory approval, or pay Baxter an amount equal to the per-unit purchase price multiplied by the amount of the shortfall. Further, the Company is obligated to reimburse Baxter for all reasonable costs directly related to work performed by Baxter in support of any change in the active pharmaceutical ingredient ("API") source or API manufacturing process.

The Supply Agreement also requires the Company to fund specified improvements at Baxter's manufacturing facility and purchase certain equipment for use by Baxter in manufacturing Ofirmev. As of December 31, 2009, the Company has reimbursed Baxter for a portion of the facility improvements and has expensed the costs as they have been incurred. The equipment purchased for the manufacturing of Ofirmev to which the Company retains title is being capitalized as it has alternative future uses and will be amortized over the life of the equipment. At the time of termination, the Supply Agreement requires the Company to reimburse Baxter for all reasonable costs for the de-installation of the Company's equipment and the restoration of Baxter's manufacturing facility to its pre-installation condition. The Company is not able to reasonably estimate the cost and the timing of these expenses at this time and therefore cannot reasonably estimate the fair value of the retirement obligation.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

In anticipation of the execution of the Supply Agreement, the Company entered into an irrevocable standby letter of credit in favor of Baxter in January 2007. The letter of credit was for an initial amount of $3,268,000 and was based on anticipated costs to be incurred by Baxter for the improvements at Baxter's manufacturing facility and the purchase of equipment to be used by Baxter in the manufacturing of the finished drug product. Under the terms of the Supply Agreement, the amount of the letter of credit may be reduced on a quarterly basis following the execution of the Supply Agreement for the costs the Company has reimbursed Baxter to fund the specified facility improvements or equipment purchases. As of December 31, 2009, at the request of the Company and based upon the costs reimbursed to Baxter by the Company, the letter of credit had been reduced by $2,268,000 to $1,000,000. The letter of credit in favor of Baxter is collateralized by a certificate of deposit which may be drawn down in part or in whole by Baxter in the event the Company fails to perform its obligations to fund the specified facility improvements or equipment purchases. As of December 31, 2009, the certificate of deposit, classified as restricted cash on the Company's balance sheets, had been reduced to $1,000,000 in accordance with the reduction in the letter of credit.

Solvay SA

As a result of the discontinuation of the Company's development program for omiganan pentahydrochloride and the termination of its license agreement with Migenix for this product candidate, on May 8, 2009, the Company notified Solvay of its intention to terminate the long-term supply agreement for the active ingredient in omiganan pentahydrochloride and a related license agreement between the Company and Solvay. The termination of the long-term supply agreement and related license agreement became effective on July 7, 2009. No charges were incurred from the termination of these agreements.

Corporate Credit Card

In 2009, the Company entered into a pledge agreement pursuant to the establishment of a corporate credit card program whereby the Company pledged $150,000 in a certificate of deposit as collateral. These funds are therefore classified as restricted cash on the Company's balance sheet at December 31, 2009.

8. License Agreements and Acquired Development and Commercialization Rights

In March 2006, the Company in-licensed the technology and the exclusive development and commercialization rights to its Ofirmev product candidate in the U.S. and Canada from Bristol-Myers Squibb Company ("BMS"). BMS sublicensed these rights to the Company under a license agreement with SCR Pharmatop S.A. As consideration for the license, the Company paid a $25,000,000 up-front fee, and may be required to make future milestone payments totaling up to $40,000,000 upon the achievement of various milestones related to regulatory and commercial events, including payments totaling $15,000,000 upon the approval of the Company's NDA for Ofirmev. In addition, the Company is obligated to pay a royalty on net sales of the licensed products and has the right to grant sublicenses to third parties. All payments made to date related to the BMS agreement have been recognized as research and development expense.

In July 2004, the Company in-licensed from Migenix the technology and the exclusive development and commercialization rights to its omiganan pentahydrochloride product candidate for the prevention and treatment of device-related, wound-related and burn-related infections in North America and Europe. As a result of the discontinuation of the omiganan pentahydrochloride development program, on May 8, 2009, the Company terminated the collaboration and license agreement between the Company and Migenix for this product candidate. No charges were incurred from the termination of this agreement. The Company has disclosed the final results of its Phase III clinical trial of omiganan pentahydrochloride in several scientific forums and intends to complete its other regulatory obligations related to the closure of this study.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

9. Stockholders' Equity

Private Placement

In February 2009, the Company issued 12,039,794 shares of its common stock at a purchase price of $7.13 per share pursuant to a private placement. In addition to the shares of the Company's common stock, warrants to purchase up to 6,019,897 additional shares of the Company's common stock were also issued as part of the transaction at a price of $0.125 per warrant. Each warrant is immediately exercisable and has a five-year term. The warrants may be exercised through either cash or net exercise for one share of common stock at a price of $7.84. The warrants were determined to be indexed to the Company's stock and therefore have been accounted for as permanent equity as they qualify as a scope exception for derivative accounting. As of December 31, 2009, all warrants related to the private placement were outstanding.

The private placement raised proceeds, net of offering costs, of $86,242,720. The purchasers in the offering consisted of new investors and existing stockholders of the Company, including six funds affiliated with three directors of the Company. In March 2009, the Company filed a registration statement covering the resale of the shares of common stock acquired by the investors in this offering, which was declared effective by the SEC in May 2009. The Company is required to maintain the effectiveness of the registration statement and may be subject to liquidated damages of one percent per month of the aggregate purchase price of the common shares then held by the investor that are registrable securities, subject to an aggregate cap of eight percent per calendar year. The Company has not recorded a liability for the potential damages associated with these liquidated damages provisions, as it does not currently believe that the transfer of consideration is probable under the agreement.

Shelf Registration

On November 30, 2007, the Company filed a shelf registration statement (the "Common Stock Registration Statement") that was declared effective by the SEC on December 11, 2007. The Common Stock Registration Statement authorized the Company to sell shares of its common stock from time to time in one or more offerings, with an aggregate offering price of up to $100,000,000. In February 2008, the Company issued 9,240,307 shares of its common stock at a purchase price of $5.34 per share pursuant to a registered direct offering under the Common Stock Registration Statement. The registered direct offering raised proceeds, net of offering costs, of $49,139,017 and the purchasers in the offering consisted of new investors and existing stockholders, including executive officers and directors of the Company. On September 4, 2009, the Company filed a universal shelf registration statement (the "Universal Shelf Registration Statement") to allow the Company to sell up to $100,000,000 of debt securities, preferred stock, common stock, debt warrants and equity warrants. The Universal Shelf Registration Statement was subsequently declared effective on September 17, 2009 by the SEC and as a result, the Company filed an amendment to its Common Stock Registration Statement on the same day to deregister all of the remaining shares of common stock originally registered by the Common Stock Registration Statement. This amendment to deregister the remaining shares under the Common Stock Registration Statement was declared effective by the SEC on September 18, 2009.

Equity Awards

In 2006, the Company adopted the 2006 Equity Incentive Award Plan (the "2006 Plan") in connection with the Company's initial public offering which became effective on October 24, 2006. Upon adoption of the 2006 Plan, the Company restricted future grants from its 2004 Equity Incentive Award Plan (the "2004 Plan"). The 2006 Plan initially reserved 2,100,000 shares of common stock for future issuance and allowed for the initial

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

number of reserved shares to be increased by (i) the 90,772 shares of common stock that remained available for issuance under the 2004 Plan as of the effective date of the 2006 Plan and (ii) the number of shares under the 2004 Plan that are repurchased, forfeited, expired or cancelled on or after the effective date of the 2006 Plan. As of December 31, 2009, options to purchase 74,753 shares issued under the 2004 Plan have been repurchased, forfeited and/or cancelled since the effective date of the 2006 Plan, increasing the number of shares reserved for issuance under the 2006 Plan accordingly.

Beginning on January 1, 2008, the 2006 Plan allows for an annual increase in the number of shares available for issuance under the 2006 Plan by the lesser of (i) 4% of the outstanding common stock on January 1 and (ii) a lesser amount determined by the board of directors, subject to an aggregate of 20,000,000 shares of common stock that may be issued over the 10-year term of the 2006 Plan. At January 1, 2009 and 2008, the board of directors approved the amount of shares authorized for future issuance under the 2006 Plan to be increased by 1,269,576 shares and 1,018,939 shares, respectively, under this provision.

As of December 31, 2009, the Company had issued both stock options and restricted stock units under the 2006 Plan and only stock options under the 2004 Plan. The following table presents shares authorized, available for future grant and outstanding under each of the Company's plans at December 31, 2009:

	Authorized	Available	Outstanding
2004 Equity Incentive Plan	2,709,475	—	1,506,281
2006 Equity Incentive Plan	4,554,040	687,224	3,861,207
	7,263,515	687,224	5,367,488

Stock Options

Stock options granted under the 2006 Plan expire no later than 10 years from the date of grant and generally vest over a four-year period. Vesting generally occurs at the rate of 25% at the end of the first year, and thereafter in 36 equal monthly installments. The exercise price of incentive stock options shall not be less than 100% of the fair value of the Company's common stock on the date of grant. The exercise price of any option granted to a 10% stockholder may not be less than 110% of the fair value of the Company's common stock on the date of grant. The Company issues new shares of common stock upon exercise of stock options.

The following table summarizes the Company's stock option activity as of December 31, 2009, and changes for the year then ended:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life - Years	Aggregate Intrinsic Value
Options outstanding at beginning of period	3,629,430	$ 6.33		
Granted	1,787,250	$ 9.28		
Exercised	(80,809)	$ 1.49		
Cancelled	(118,133)	$ 10.64		
Options outstanding at end of period	5,217,738	$ 7.32	8.00	$16,842,739
Options exercisable at end of period	2,528,920	$ 5.73	7.02	$13,403,226

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

The aggregate intrinsic value of options exercised during 2009, 2008 and 2007 was $699,523, $71,556 and $332,642, respectively. As of December 31, 2009, 8,144 shares acquired through the early exercise of options were subject to repurchase by the Company until they vest in accordance with the vesting schedule applicable to the underlying option.

Restricted Stock Units

In August 2009, the Company granted a total of 300,500 restricted stock units ("RSUs") to certain officers and employees. One-half of the RSUs were to vest upon the approval by the FDA of the Company's NDA for Ofirmev, if such approval occurred prior to December 31, 2009. At December 31, 2009, the Company had not received approval of its Ofirmev NDA and therefore the performance criteria for these grants was not achieved. As such, the awards were forfeited and all previously recorded expense associated with these RSUs was recovered. The remaining half of the RSUs vest upon the first anniversary of the NDA approval by the FDA, if such approval is received. These RSUs continue to be outstanding as of December 31, 2009 at an intrinsic value of $1,448,083. The Company will issue new shares of common stock upon the vesting of the RSUs.

The following table summarizes the Company's RSU activity as of December 31, 2009, and changes for the year then ended:

	Shares	Weighted-Average Grant Date Fair Value per Share
Restricted stock units outstanding at beginning of period	—	$ —
Granted	300,500	$ 10.91
Vested	—	$ —
Cancelled	(1,000)	$ 10.91
Forfeited	(149,750)	$ 10.91
Restricted stock units outstanding at end of period	149,750	$ 10.91

10. Income Taxes

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company's tax years for 2004 and forward are subject to examination by the Federal and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrued interest and/or penalties related to income tax matters in the Company's balance sheets at December 31, 2009 and 2008, and has recognized no interest and/or penalties in the Company's statement of operations for the years ended December 31, 2009, 2008 and 2007, respectively.

On January 1, 2008, the Company adopted authoritative guidance relating to the accounting for uncertainty in income taxes. The guidance clarified the recognition threshold and measurement attributes for financial statement disclosure of tax positions taken, or expected to the taken, on a tax return. The impact of an uncertain income tax provision on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has a less than 50% likelihood of being sustained. On the date of adoption, there were no unrecognized tax benefits. Further, there are no unrecognized tax benefits included in the Company's balance sheet at December 31, 2009 and 2008, respectively.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Until this analysis has been completed, the Company has removed the deferred tax assets for net operating losses of approximately $69,631,000 and research and development credits of approximately $5,043,000 generated through 2009 from its deferred tax asset schedule, and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits accordingly. The Company does not expect this analysis to be completed within the next 12 months and, as a result, the Company does not expect that the unrecognized tax benefits will change within 12 months of this reporting date. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

Significant components of the Company's deferred tax assets for federal and state income taxes at December 31, 2009 and 2008 are shown below. A valuation allowance has been established as realization of such deferred tax assets has not met the more likely than not threshold requirement.

	As of December 31,	
	2009	2008
Deferred tax assets:		
Net operating loss carryforwards	$ —	$ —
Tax credit carryforwards	—	—
Capitalized in-process research and development	7,963,000	8,726,000
Stock-based compensation	5,851,000	3,569,000
Other, net	2,165,000	990,000
	15,979,000	13,285,000
Valuation allowance for deferred tax assets	(15,979,000)	(13,285,000)
Net deferred tax assets	$ —	$ —

A reconciliation of the Company's effective tax rate and federal statutory tax rate is as follows:

	As of December 31,		
	2009	2008	2007
Federal income taxes	35.0%	35.0%	35.0%
State income taxes	5.8%	5.8%	5.8%
Research and development credits	2.4%	3.5%	1.1%
Stock-based compensation	(1.7)%	(1.2)%	(1.0)%
Change in federal valuation allowance	(5.9)%	(1.7)%	27.6%
Prior year true-up	2.3%	—	—
Removal of net operating loss and research and development tax credits	(37.4)%	(41.1)%	(68.2)%
Other, net	(0.5)%	(0.3)%	(0.3)%
	0.0%	0.0%	0.0%

At December 31, 2009, the Company had federal and state net operating loss carryforwards of approximately $171,444,000 and $170,600,000, respectively. The federal and state tax loss carryforwards will begin to expire in 2024 and 2014, respectively, unless previously utilized. The Company also had federal

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

research and development tax credit carryforwards of approximately $3,836,000 which will begin expiring in 2024 unless previously utilized, and state research and development tax credit carryforwards of approximately $1,857,000 which carryforward indefinitely.

Included in the net operating loss carryforwards is approximately $435,000 of losses attributable to excess stock option deductions. Under current accounting guidance concerning when tax benefits related to excess stock option deductions can be credited to paid in capital, the related valuation allowance cannot be reversed, even if the facts and circumstances indicate that it is more likely than not that the deferred tax asset can be realized. The valuation allowance will only be reversed as the related deferred tax asset is applied to reduce taxes payable.

11. Employee Benefit Plan

The Company has a qualified retirement plan under the provisions of Section 401(k) of the Internal Revenue Code covering substantially all employees. Employees may contribute up to 100% of their annual compensation up to the maximum annual amount prescribed by the Internal Revenue Service. The Company may elect to make a discretionary contribution or match a discretionary percentage of employee contributions. During 2009, 2008 and 2007, the Company elected not to make any contributions to the plan.

12. Summarized Quarterly Data (Unaudited)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for the years ended December 31, 2009 and 2008 are as follows:

	Fiscal Year 2009 Quarters				
	1st[3]	2nd	3rd	4th	Total
Total operating expenses	$ 10,137,990	$ 8,003,022	$ 11,295,126	$ 15,060,495	$ 44,496,633
Net loss	$ (10,437,363)	$ (8,300,081)	$ (11,441,105)	$ (15,312,390)	$ (45,490,939)
Basic and diluted net loss per share[1][2]	$ (0.24)	$ (0.17)	$ (0.23)	$ (0.30)	$ (0.93)

	Fiscal Year 2008 Quarters				
	1st	2nd	3rd	4th[4]	Total
Total operating expenses	$ 13,757,044	$ 15,573,390	$ 13,660,659	$ 13,541,370	$ 56,532,463
Net loss	$ (13,716,915)	$ (15,596,836)	$ (13,748,995)	$ (14,036,104)	$ (57,098,850)
Basic and diluted net loss per share[1][2]	$ (0.42)	$ (0.41)	$ (0.36)	$ (0.37)	$ (1.55)

(1) Loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly net loss per share may not necessarily equal the total for the year.

(2) In the first quarter of 2009, the Company issued 12,039,794 shares of common stock pursuant to a private placement. In the first quarter of 2008 the Company issued 9,240,307 shares of its common stock pursuant to the shelf registration. As a result, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented.

(3) During the first quarter of 2009, the Company recorded a restructuring charge of $650,786 related to the discontinuation of its omiganan pentahydrochloride development program. This charge was reduced by $64,219 as of December 31, 2009 as the actual costs incurred were less than anticipated.

(4) During the fourth quarter of 2008, the Company recorded an impairment charge of $2,353,162 related to its omiganan pentahydrochloride manufacturing assets. During 2009, the Company recorded adjustments to the impairment charge taken on the manufacturing equipment, reducing the charge by $180,926 as actual costs incurred in disposing a portion of the assets were less than anticipated.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934, as amended, (the "Exchange Act") is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. Management has determined that there were no significant changes to our internal control over financial reporting during the year or quarter ended December 31, 2009 that has materially effected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining an adequate system of internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and as implemented in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles general accepted in the U.S. All internal control systems, no matter how well designed, have inherent limitations. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit 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 directors of the company; and
- 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 company's financial statements.

Management has adopted the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") framework to evaluate the effectiveness of our internal control over financial reporting. Management's evaluation of the results of testing included consideration of susceptibility to loss or fraud, subjectivity, complexity, the extent of judgment, the amount and volume of the transactions exposed to the deficiency, the existence of mitigating controls, the cause of detected exceptions, how the exception was detected, the pervasiveness of the exception, the significance of the deviation from policy and the frequency of exceptions relative to the frequency of operation.

Indicators of deficiencies that may be material weaknesses and are at least significant include restatement, material misstatement in the current period, ineffective Audit Committee oversight, ineffective internal audit function, identification of fraud of any magnitude by management, significant deficiencies that remain uncorrected for some period of time, ineffective control environment, and the aggregate effect of all deficiencies.

As of December 31, 2009, management assessed the effectiveness of our internal control over financial reporting, and concluded that such control over financial reporting was effective and there were no material weaknesses in our internal control over financial reporting that have been identified by management. Our independent registered public accounting firm, Ernst & Young LLP, has issued an audit report on the effectiveness of our internal control over financial reporting as of December 31, 2009 and is included below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Board of Directors and
Stockholders of Cadence Pharmaceuticals, Inc.

We have audited Cadence Pharmaceuticals, Inc.'s (a development stage company) internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Cadence Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness 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 the company's internal control over financial reporting based on our audit.

We conducted 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 about 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, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's 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 for external purposes 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, in reasonable detail, 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 permit 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 directors of the company; 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.

Because of 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 controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Cadence Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Cadence Pharmaceuticals, Inc. as of December 31, 2009 and 2008, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2009 and for the period from May 26, 2004 (Inception) through December 31, 2009, of Cadence Pharmaceuticals, Inc. and our report dated March 15, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 15, 2010

Item 9B. ***Other Information***

Not applicable.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

Information required by this item will be included under the captions *Election of Directors*, *Corporate Governance and Other Matters*, *Executive Compensation and Other Information*, and *Section 16(a) Beneficial Ownership Reporting Compliance* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2009 pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

Item 11. ***Executive Compensation***

We maintain employee compensation programs and benefit plans in which our executive officers are participants. Copies of these plans and programs are set forth or incorporated by reference as Exhibits to this report. The information required by this item will be included in our definitive Proxy Statement under the caption *Executive Compensation and Other Information* to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2009 pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

Information required by this item regarding security ownership of beneficial owners and management will be included under the caption *Security Ownership of Certain Beneficial Owners and Management* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2009 pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference. The information required this item regarding our equity compensation plan is included in Item 5 of this Annual Report on Form 10-K.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

Information required by this item will be included under the caption *Certain Relationships and Related Transactions* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2009 pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

Item 14. ***Principal Accounting Fees and Services***

Information required by this item will be included under the caption *Ratification of Selection of Independent Registered Public Accounting Firm* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2009 pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules***

(a) Documents filed as part of this report:

(1) *Financial Statements.* The following financial statements of Cadence Pharmaceuticals, Inc., together with the report thereon of Ernst & Young LLP, required to be filed pursuant to Part II, Item 8 of this Annual Report on Form 10-K, are included on pages 60 through 83, as follows*:*

(2) *Financial Statements Schedules.* All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) *Exhibits*.

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006
3.2	Amended and Restated Bylaws of the Registrant, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006
3.2.1	Amendment of Amended and Restated Bylaws of the Registrant, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 17, 2007
4.1	Form of the Registrant's Common Stock Certificate, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006
4.2	Amended and Restated Investor Rights Agreement dated February 21, 2006, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006
4.5	Registration Rights Waiver and Amendment dated November 29, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.6	Form of Warrant to Purchase Stock issued to Silicon Valley Bank on November 30, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007

Exhibit Number	Description of Exhibit
4.7	Form of Warrant to Purchase Stock issued to Oxford Finance Corporation on November 30, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.8	Form of Warrant to Purchase Stock issued to GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.), on November 30, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.9	Form of Warrant to Purchase Stock issued on February 18, 2009, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 20, 2009
10.1#	Form of Director and Executive Officer Indemnification Agreement, incorporated herein by reference to the corresponding exhibit to Amendment No. 1 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on August 30, 2006
10.3#	2004 Equity Incentive Award Plan and forms of option agreements thereunder, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-8 (File No. 333-138226) as filed with the SEC on October 26, 2006
10.5#	2006 Equity Incentive Award Plan and forms of option and restricted stock agreements thereunder, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-8 (File No. 333-138226) as filed with the SEC on October 26, 2006
10.6	Form of Amended and Restated Restricted Common Stock Purchase Agreement, incorporated herein by reference to the corresponding exhibit to Amendment No. 1 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on August 30, 2006
10.9	Lease dated May 12, 2006 by and between the Registrant and Prentiss/Collins Del Mar Heights LLC, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006
10.11†	IV APAP Agreement (U.S. and Canada) dated February 21, 2006 by and between the Registrant and Bristol-Myers Squibb Company, incorporated herein by reference to the corresponding exhibit to Amendment No. 2 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on September 25, 2006
10.12†	License Agreement dated December 23, 2002 by and among SCR Pharmatop and Bristol-Myers Squibb Company, incorporated herein by reference to the corresponding exhibit to Amendment No. 2 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on September 25, 2006
10.13†	Loan and Security Agreement dated February 17, 2006 by and among the Registrant, Silicon Valley Bank and Oxford Finance Corporation, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006
10.16†	Amendment No. 1 dated October 6, 2006 to Collaboration and License Agreement dated July 30, 2004 by and between the Registrant and Migenix, Inc. (formerly Micrologix Biotech Inc.), incorporated herein by reference to the corresponding exhibit to Amendment No. 3 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on October 10, 2006
10.17†	Development and Supply Agreement by and between Cadence Pharmaceuticals, Inc. and Baxter Healthcare Corporation dated July 18, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on July 23, 2007

Exhibit Number	Description of Exhibit
10.20	Second Amendment to Loan and Security Agreement dated November 30, 2007 by and among the Company and Oxford Finance Corporation, Silicon Valley Bank and Merrill Lynch Capital, a Division of Merrill Lynch Business Financial Services Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
10.24	Form of Common Stock Purchase Agreement dated February 14, 2008, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 15, 2008
10.27#	Second Amended and Restated Cadence Pharmaceuticals, Inc. Director Compensation Policy, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2008 as filed with the SEC on November 7, 2008
10.30	Securities Purchase Agreement, dated February 13, 2009, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 20, 2009
10.31#	Form of Second Amended and Restated Employment Agreement.), incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33103) for the year ended December 31, 2008 as filed with the SEC on March 16, 2009
10.32#	2009 Corporate Bonus Plan, incorporated herein by reference to the corresponding exhibit to the Registrant's Annual Report on Form 10-K (File No. 001-33103) for the year ended December 31, 2008 as filed with the SEC on March 16, 2009
10.33#	Employment Agreement between Cadence Pharmaceuticals, Inc. and Scott A. Byrd, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on June 22, 2009
10.34.1#	Form of Deferral Restricted Stock Unit Agreement under the 2006 Equity Incentive Award Plan, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on September 2, 2009
10.34.2#	Form of Non-Deferral Restricted Stock Unit Agreement under the 2006 Equity Incentive Award Plan, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on September 2, 2009
10.35#±	2010 Corporate Bonus Plan
23.1±	Consent of Independent Registered Public Accounting Firm
31.1±	Certification of Chief Executive Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2±	Certification of Chief Financial Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1±	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002

± Included in this Report.

# Indicates management contract or compensatory plan.

† Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

CADENCE PHARMACEUTICALS, INC.

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

Dated: March 15, 2010

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

Signature	Title	Date
/s/ THEODORE R. SCHROEDER **Theodore R. Schroeder**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2010
/s/ WILLIAM R. LARUE **William R. LaRue**	Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary (Principal Financial and Accounting Officer)	March 15, 2010
/s/ CAM L. GARNER **Cam L. Garner**	Chairman of the Board of Directors	March 15, 2010
/s/ BRIAN G. ATWOOD **Brian G. Atwood**	Director	March 15, 2010
/s/ SAMUEL L. BARKER, PH.D. **Samuel L. Barker, Ph.D.**	Director	March 15, 2010
/s/ MICHAEL A. BERMAN, M.D. **Michael A. Berman, M.D.**	Director	March 15, 2010
/s/ JAMES C. BLAIR, PH.D. **James C. Blair, Ph.D.**	Director	March 15, 2010
/s/ ALAN D. FRAZIER **Alan D. Frazier**	Director	March 15, 2010
/s/ TODD W. RICH **Todd W. Rich**	Director	March 15, 2010
/s/ CHRISTOPHER J. TWOMEY **Christopher J. Twomey**	Director	March 15, 2010

Exhibit 10.35

CONFIDENTIAL

CADENCE PHARMACEUTICALS, INC.

BONUS PLAN

Effective January 1, 2010

INTRODUCTION AND PURPOSE

The Cadence Pharmaceuticals, Inc. ("Cadence" or the "Company") Bonus Plan (the "Plan") is designed to reward eligible employees for the achievement of corporate objectives, as well as measured individual objectives that are consistent with and support the overall corporate objectives. Since cooperation between departments and employees will be required to achieve corporate objectives that represent a significant portion of the Plan, the Plan should help foster teamwork and build a cohesive management team.

The Plan is designed to:

- Encourage high performance by providing an incentive program to achieve overall corporate objectives and to enhance shareholder value.
- Reward those individuals who significantly impact corporate results.
- Encourage increased teamwork among all disciplines within Cadence.
- Incorporate an incentive program in the Cadence overall compensation program to help attract and retain employees.
- Provide an incentive for eligible employees to remain employed by Cadence through and beyond the payout of any earned bonus.

ELIGIBILITY

All regular, exempt employees at the Manager level or higher are eligible to participate in the Plan. Employees are not eligible if included in a separate formal incentive plan provided by the Company. In order to be eligible, a participant must have been in an eligible position for at least three (3) full consecutive months prior to the end of the Plan year, and the participant must remain employed through the end of the Plan year and until awards are paid. If the participant is not employed on the date awards are paid, the participant will not have earned any bonus. If the participant has been subject to a performance improvement plan or other disciplinary procedure during the Plan year, any award to such individual will be at the discretion of the President and CEO or the Compensation Committee.

Change in Status During the Plan Period:

a. *Participants hired during the Plan year:*

- Participants hired during the Plan year are eligible for a prorated award based the number of months employed in an eligible position.

- Participants hired after the end of the third quarter are not eligible to participate for the plan year.

b. *Promotion/change in level:*

- For promotions that occur after April 30th of the applicable Plan year but prior to October 1st of the applicable Plan year, the calculation will be prorated, based on the number of months at each bonus percentage level.
- If the promotion occurred on or after October 1st of the applicable Plan year, the entire calculation will be based on the bonus percentage applicable prior to the promotion.

c. *Transfer to a position that is included in a separate formal Incentive Plan:* Awards will be pro-rated using the same discipline as outlined for promotions above and in the formal Incentive Plan.

d. *Termination of employment:*

- If a participant's employment is terminated voluntarily prior to the date awards are paid, the participant will not be eligible to receive an award.
- If a participant's employment is terminated involuntarily prior to the date awards are paid, it will be at the absolute discretion of the Company whether or not an award payment is made.

e. *Leave of Absence:* Employee may be considered for a prorated award.

AWARD CALCULATION

Awards will be determined by applying a "bonus percentage" to the participant's base salary in effect at the end of the Plan year. While the Compensation Committee may change the bonus percentage for any Plan year, the following bonus percentages will initially be used for this purpose:

Position Title	Bonus Percentage
President/CEO	60%
EVP, SVP	35%
VP	30%
Senior Director	25%
Director	20%
Associate Director, Senior Manager	15%
Manager	10%

Corporate and Individual Performance Factors

The President and / or CEO will present to the Compensation Committee a list of the overall corporate objectives for the applicable Plan year, which are subject to approval by the Compensation Committee. All participants in the Plan will then develop a list of key individual objectives, which must be approved by the responsible Vice President or Senior Vice President and by the President and / or CEO.

The relative weight between corporate and individual performance factors varies based on the individual's assigned level within the organization. The weighting may be reviewed periodically and may be adjusted for any Plan year. The weighting for the performance factors will initially be as follows:

	Corporate	Individual
President/CEO	100%	
EVP/SVP/VP	60%	40%
Dir/Assoc Dir/Sr Mgr	50%	50%
Manager	40%	60%

Performance Award Multiplier

Separate award multipliers will be established for both the corporate and the individual components of each award. The award multiplier for the corporate component shall be determined by the Compensation Committee each Plan year, in its sole discretion. The same award multiplier for the corporate component of the award shall be used for all Plan participants. The award multiplier for the individual component shall be determined by the responsible Vice President or Senior Vice President and by the President and / or CEO.

While the Compensation Committee may change the award multipliers for any Plan year, the following scale will be used to determine the actual performance award multiplier based upon the measurement of corporate and individual performance objectives.

	Performance Category	Award Multiplier
1.	Performance for the year met or exceeded objectives or was excellent in view of prevailing conditions	75% - 150%
2.	Performance generally met the year's objectives or was very acceptable in view of prevailing conditions	50% - 100%
3.	Performance for the year met some, but not all, objectives	25% - 50%
4.	Performance for the year was not acceptable in view of prevailing conditions	0%

Example

The example below shows a sample cash bonus award calculation under the Plan, which is determined after the end of the performance period.

Step #1: A potential base bonus award is calculated by multiplying the employee's base salary by their assigned level bonus percentage.

Step #2: The calculated potential base bonus amount is then split between the corporate and individual performance factors by the employee's assigned level (per the weighting above). This calculation establishes specific potential dollar awards for the performance period based on both the individual and corporate performance factor components.

Step #3: After the end of the performance period, corporate and individual award multipliers will be established using the criteria described above. Awards are determined by multiplying the potential bonus awards in Step #2 by the actual corporate and individual award multipliers.

Example: *Step # 1:* Potential Bonus Award Calculation

Position:		Director	
Base salary:		$100,000	
Target bonus percentage:		20%	
Potential base bonus:		$ 20,000	
Step # 2: Split award target amount based on weighting of Performance Factors			
Potential corporate performance bonus (50%):		$ 10,000	
Potential individual performance bonus (50%):		$ 10,000	
Step # 3: Actual Cash Incentive Award Calculation			
Assumed payment multipliers based on assessment of corporate and individual performance:			
Corporate multiplier	75%-performance generally met objectives		
Individual multiplier	125%-performance generally exceeded objectives		
Cash Award:			
Corporate component		$ 7,500	($10,000 x 75%)
Individual component		$ 12,500	($10,000 x 125%)
Total Award		$ 20,000	

AWARD PAYMENTS

Bonus award payments may be made in cash, through the issuance of stock, stock options or another form of equity award, or by a combination of cash, stock, stock options and/or another form of equity award, at the discretion of the Compensation Committee. All bonus award payments are subject to applicable tax withholdings. In the event that the Compensation Committee and / or the Board of Directors elect to pay bonus awards in stock or stock options, the Compensation Committee, in its sole discretion, will make a determination as to the number of shares of stock or stock options to be issued to each Plan participant based, in part, upon the overall corporate performance and each participant's individual performance, as described. The issuance of stock and stock options may also be subject to the approval of the Company's stockholders, and any stock options issued will be subject to the terms and conditions of the Company's Equity Incentive Award Plan, as amended from time to time by the Company.

Payment of bonus awards will be made as soon as practicable after the issuance of the Company's year-end audited Financial Statements for the Plan year, but not later than December 31 of the year following the Plan year. Payments will not be impacted by any benefits, with the exception of elected 401(k) contributions which will be applied.

PLAN PROVISIONS

Governance

The Plan will be governed by the Compensation Committee of the Board of Directors (the "Compensation Committee"). The President and / or CEO of Cadence will be responsible for the administration of the Plan. The Compensation Committee will be responsible for approving any compensation or incentive awards to officers of the Company. All determinations of the Compensation Committee, under the Plan, shall be final and binding on all Plan participants.

Compensation Committee's Absolute Right to Alter or Abolish the Plan

The Compensation Committee reserves the right in its absolute discretion to abolish the Plan at any time or to alter the terms and conditions under which incentive compensation will be paid. Such discretion may be exercised any time before, during, and after the Plan year is completed. No participant shall have any vested right to receive any compensation hereunder until actual delivery of such compensation. Participation in the Plan at any given time does not guarantee ongoing participation.

Employment Duration/Employment Relationship

This Plan does not, and Cadence's policies and practices in administering this Plan do not, constitute an express or implied contract or other agreement concerning the duration of any participant's employment with the Company. The employment relationship of each participant is "at will" and may be terminated at any time by Cadence or by the participant, with or without cause.

Any questions pertaining to this plan should be directed to the Human Resources Department.

Cadence Pharmaceuticals, Inc.

Bonus Plan

Effective January 1, 2010

This is to acknowledge that I have received a copy of the **2010 Bonus Plan**.

Name: _____ Date: _____

(Print)

_____

(Signature)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements on Form S-8 (Nos. 333-163941 and 133-138226) and Form S-3 (Nos. 333-161756, 33-158126 and 333-147721) of Cadence Pharmaceuticals, Inc. and in the related Prospectuses of our reports dated March 15, 2010, with respect to the financial statements of Cadence Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Cadence Pharmaceuticals, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2009.

/s/ Ernst & Young LLP

San Diego, California
March 15, 2010

Exhibit 31.1

CERTIFICATION

I, Theodore R. Schroeder, certify that:

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

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

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

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

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

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

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

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

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

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

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

/S/ THEODORE R. SCHROEDER

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

Date: March 15, 2010

Exhibit 31.2

CERTIFICATION

I, William R. LaRue, certify that:

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

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

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

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

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

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

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

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

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

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

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

/S/ WILLIAM R. LARUE

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

Date: March 15, 2010

Exhibit 32.1

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

In connection with the filing of the Annual Report on Form 10-K of Cadence Pharmaceuticals, Inc. ("Cadence") for the year ended December 31, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of Cadence, hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that, to our knowledge:

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

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

The undersigned have executed this Certification effective as of March 15, 2010.

/S/ THEODORE R. SCHROEDER

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

/S/ WILLIAM R. LARUE

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of Cadence, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to Cadence and will be retained by Cadence and furnished to the Securities and Exchange Commission or its staff upon request.