

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, 2011

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  
(State or other jurisdiction  
of incorporation or organization)

41-2142317  
(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  
(Title of class)

NASDAQ Global Market  
(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

Non-accelerated filer

Smaller reporting company

(Do not check if a 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, 2011, the last business day of the Registrant's second fiscal quarter, reported on the NASDAQ Global Market, was approximately \$125,600,000. 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 29, 2012, there were 85,516,607 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 2012 Annual Meeting of Stockholders, which is scheduled to be held on June 13, 2012. 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, 2011.

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### 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 report.*

*This 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 “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the caption “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.*

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**CADENCE PHARMACEUTICALS, INC.**  
**Annual Report on Form 10-K**  
**For the Fiscal Year Ended December 31, 2011**

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## PART I

### Item 1. *Business*

#### Company Overview

We are a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting. We currently have rights to one product, OFIRMEV® (acetaminophen) injection, a proprietary intravenous, or IV, formulation of acetaminophen. We in-licensed the exclusive United States, or U.S., and Canadian rights to OFIRMEV from Bristol-Myers Squibb Company, or BMS, which sells intravenous acetaminophen in Europe and other markets for the treatment of acute pain and fever under the brand name Perfalgan®. In November 2010, the U.S. Food and Drug Administration, or FDA, granted marketing approval for OFIRMEV, which is indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever in adults and children two years of age and older. We launched commercial sales of OFIRMEV in the U.S. in January 2011.

We believe that OFIRMEV fills significant unmet medical needs and that the hospital pharmaceuticals market is both concentrated and underserved. We have established a 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 unmet commercial potential.

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](http://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 100 F Street, N.E., Washington, D.C. 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's website at [www.sec.gov](http://www.sec.gov).

We own or have rights to various trademarks, copyrights and tradenames used in our business, including the following: Cadence®, OFIRMEV® and the OFIRMEV logo. This report also contains trademarks of others, including Caldolor®, DepoDur®, IONSYSTM, 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 acquisition, in-licensing, development and commercialization of proprietary pharmaceuticals principally for use in the hospital setting. Our near-term strategy is to work directly with physicians and hospitals to increase demand for OFIRMEV. Longer-term, our strategy is to acquire, in-license, 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 unmet commercial potential. We will also consider strategically attractive opportunities to co-promote commercialized hospital products. Specifically, we intend to:

- *Successfully expand the sales of OFIRMEV.* We are working to increase demand for OFIRMEV and gain additional formulary approvals at hospitals throughout the U.S. Our sales force is equipped with promotional materials and our medical science liaisons have been provided with medical education materials to inform and educate hospital-based physicians who treat patients with mild to severe pain and fever. We have entered into agreements with major pharmaceutical wholesalers to supply OFIRMEV across the U.S. through their distribution centers.

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- *Build a highly leverageable sales organization targeting hospitals.* We have established a sales force that is focused on promoting OFIRMEV to hospitals throughout the U.S. The number of institutions comprising the hospital marketplace is relatively limited, and because of this, 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 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 any product candidates we may acquire or in-license 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 and commercial hospital products with attractive potential.* In June 2010, we entered into an option agreement that granted us an exclusive, irrevocable option to purchase Incline Therapeutics, Inc., or Incline, which is developing IONSYS™ (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery. 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 unmet commercial potential. In addition, we will also consider strategically attractive opportunities to co-promote commercial hospital products that would be complementary to our existing business or that otherwise have attractive potential.
- *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.

### **Commercialization Strategy**

We believe that we can achieve our strategic goals by deploying our experienced sales organization, supported by our internal marketing infrastructure, to promote our products to hospitals that have 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 setting, where appropriate.

#### ***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.

U.S. hospitals accounted for approximately \$52 billion or 14% of U.S. pharmaceutical sales in 2010, according to Wolters Kluwer Pharma Solutions, an independent marketing research firm. Furthermore, we believe pharmaceutical sales to acute care hospitals are highly concentrated among a relatively small number of large institutions. For example, 1,800 to 1,900 of the approximately 7,000 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

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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. Thus, a single sales representative can effectively promote products from multiple therapeutic categories to multiple prescribers within the institution. Furthermore, drug sampling generally does not occur in hospitals, which represents a significant cost advantage versus marketing to office-based physicians.

### ***Formulary Adoption***

We believe an important initial step to broad market acceptance for OFIRMEV is being approved for addition to hospitals' lists of approved drugs, or formulary lists. In general, our experience is that the process for adding a new medication, such as OFIRMEV, to a hospital's formulary list begins with that institution's Pharmacy and Therapeutics Committee, or P&T committee.

The P&T committee is the nucleus of the decision making process and can consist of up to 10-20 professionals, including members of various hospital disciplines. They generally meet on a monthly or bimonthly basis to review drugs and medication guidelines. Once a request is made to add a medication to a formulary, it can take anywhere between one and twelve months to schedule the meeting. On average, a company like ours will have several interactions with committee members prior to formulary acceptance, providing information and answering questions that may arise during the committee's deliberations. The primary tools that support our conversations with P&T committees regarding OFIRMEV are the clinical data that support our claims of significant pain relief, decreased opioid consumption and improved patient satisfaction. Additionally, we can provide P&T committee members with published clinical studies of IV acetaminophen, which may be useful to the committees in their evaluation of the clinical benefits and potential hospital cost savings. As a result of our efforts to obtain formulary approvals in key institutions for OFIRMEV, as of December 31, 2011, the product had been added to the formulary lists of approximately 1,580 hospitals.

After a drug, such as OFIRMEV, is approved on a hospital's formulary list, it may require additional time for the hospital to order the product and incorporate it into its systems and procedures in order to facilitate the routine use of the product by physicians. We have developed and are implementing new marketing and sales strategies designed to support the rapid implementation of OFIRMEV into these systems and procedures. We anticipate that broad physician access to OFIRMEV will lead to accelerating sales.

### **Sales and Marketing**

We have established a sales force of hospital sales specialists that is supported by an experienced commercial management, marketing and sales operations team. Additionally, our field-based medical science liaisons inform and educate hospital-based physicians regarding the appropriate uses of OFIRMEV.

The primary target audience for OFIRMEV includes anesthesiologists and surgeons. Other targets include certified registered nurse anesthetists, emergency medicine physicians, intensivists, internists, hospitalists, obstetricians and other physicians throughout the hospital, as well as hospital-based pharmacists. Our commercial sales force is focused on reaching the top 1,800 to 1,900 U.S. hospitals, which we believe represent approximately 80% of the market opportunity for OFIRMEV.

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We believe that our sales force is differentiated by its level of experience and background in the industry. Our sales management team has an average of more than 15 years of pharmaceutical industry experience, and an average of more than eight years of hospital sales management experience. We 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 includes 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 addresses those needs.

Field-based regional business directors and district sales managers provide oversight for our hospital sales specialists and direct our efforts to provide hospital customers with the information needed to obtain formulary approval for, and increase utilization of, OFIRMEV. 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 assists physicians in using OFIRMEV safely and effectively. In addition to our hospital sales specialists, we 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.

### ***Intravenous Acetaminophen and U.S. Market Opportunity***

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. We believe these and other countries are utilizing intravenous acetaminophen as the foundation for multi-modal analgesia, particularly in the post-operative setting.

Prior to the commercial launch of OFIRMEV in January 2011, the U.S. IV analgesic therapy market consisted of opioids, such as morphine, meperidine, hydromorphone and fentanyl, and two NSAIDs. These two NSAIDs, Toradol (ketorolac tromethamine), a generic form of which is also available in the U.S. from a number of manufacturers, and Caldolor (ibuprofen), represented the only non-opioid IV analgesics available for treating acute pain in adults in the U.S. prior to OFIRMEV. According to Wolters Kluwer Pharma Solutions, approximately 270 million vials of injectable analgesics were sold in the U.S. in 2010. 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 in 2010. We have set the list price, or wholesale acquisition cost, of OFIRMEV at \$10.75 per vial. We have signed agreements with several group purchasing organizations, including the five largest, to provide services and discounted pricing. Our pricing strategy is intended to allow hospitals to access OFIRMEV at a fair price while facilitating prompt formulary adoption at many institutions.

We believe that the key product attributes that will drive the adoption of OFIRMEV in the U.S. include the efficacy and safety profile of the product, as demonstrated in multiple clinical studies, the established 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, improved patient satisfaction, and the desire for a dosage form for patients unable to take medication orally.

## **Marketed Product**

### ***OFIRMEV Product Overview***

The FDA approved OFIRMEV, our proprietary intravenous formulation of acetaminophen, in November 2010 for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever in adults and children two years of age and older.

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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, prior to the commercial launch of OFIRMEV in January 2011, there was no intravenous formulation available in the U.S. for patients who were unable to take medications by mouth, required faster onset of pain relief or fever reduction, or for whom it was 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. Additionally, absorption of oral analgesics may be compromised following surgery due to factors such as delays in gastric functioning and opioid-related pyloric narrowing or closure. As a result, published clinical studies have shown that dosing with IV acetaminophen provided higher plasma concentrations of the drug than oral administration. Prior to the approval of OFIRMEV, only two classes of injectable analgesics, opioids and non-steroidal anti-inflammatory drugs, or NSAIDs, were available in the U.S. for the treatment of pain.

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.



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Other than OFIRMEV, 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. Caldolor is not approved for pediatric use, and ketorolac is only approved for use as a single dose in children greater than two years of age. 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. 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 adverse effects. NSAIDs such as ketorolac and ibuprofen exert a direct inhibitory effect on platelet aggregation, which could result in increased bleeding susceptibility in the post-operative setting. These NSAIDs are often avoided in surgical patients because they may be associated with renal toxicity, particularly in patients with compromised renal function or hypoperfusion. NSAIDs may also be associated with gastric irritation and gastric bleeding, and an increased incidence of cardiovascular adverse events have been found to be associated with postoperative use of certain 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.

### ***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), and Ultram (tramadol 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. As the only IV formulation of acetaminophen available in the U.S., OFIRMEV provides the only option to extend this common multi-modal approach to the peri-operative setting when patients are unable to take oral medications.

### ***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 100.4 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

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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 are 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 has been reported to be associated with Reye's syndrome, a potentially fatal disease, in children and teenagers with viral infections.

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., OFIRMEV is the only available intravenous form of acetaminophen, and aspirin is currently not 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.

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. offers a significant treatment option for hospitalized patients with fever and addresses unmet medical needs, particularly with respect to the management of fever in children two years of age and older.

### ***Clinical Development***

In November 2010, the FDA granted marketing approval for OFIRMEV. OFIRMEV is indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever in adults and children two years of age and older. We submitted our new drug application, or NDA, for OFIRMEV under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. This approach allows at least some of the information required for approval to come 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 included data from our own clinical trials in the U.S., trials of IV acetaminophen previously completed by BMS in the U.S. and Europe, and other studies published in the scientific and medical literature.

The approval of OFIRMEV was supported by the results of 20 clinical trials involving 1,375 patients. Procedure types included, but were not limited to, orthopedic surgery (including total hip or knee replacement), gynecologic surgery, general surgery, ear, nose, and throat surgery, and cardiothoracic surgery. Across this

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clinical data set, IV acetaminophen showed a significant and reproducible benefit in analgesia as measured by a variety of endpoints relating to pain relief or reduction in pain intensity. Importantly, several studies demonstrated that including IV acetaminophen in the analgesic regimen resulted in significant reductions in opioid consumption. The clinical benefit of reduced opioid consumption was not demonstrated. There are three pivotal clinical trials that supported our NDA for OFIRMEV and are currently included in the OFIRMEV prescribing information.

### Adult Pain Study 1, RC 210 3 002 / Sinatra Study (BMS)

This was a phase III, randomized, double-blind, placebo-controlled, multicenter study that evaluated the analgesic efficacy and safety of single and repeated doses of OFIRMEV 1 g in comparison with placebo in 101 patients experiencing moderate to severe pain following total hip or knee replacement. Patients were allowed rescue medication with patient-controlled analgesia, or PCA, morphine.

- *Pain Relief and Pain Intensity.* In a 6-hour, single-dose evaluation period, OFIRMEV 1 g + PCA morphine demonstrated superior pain relief vs. placebo + PCA morphine (15 minutes through 6 hours,  $P < 0.05$ ). In a repeated-dose evaluation period, OFIRMEV showed a greater reduction in pain intensity over 24 hours (SPID24) compared to placebo ( $P < 0.001$ ).
- *Morphine Consumption.* OFIRMEV 1 g + PCA morphine significantly reduced morphine consumption vs. placebo + PCA morphine alone (–46% after first dose,  $P < 0.01$ ; –33% over 24 hours,  $P < 0.01$ ). Median time to first rescue medication was significantly longer with OFIRMEV 1 g compared with placebo (3 hours vs. 0.8 hours,  $P = 0.0001$ ). The clinical benefit of reduced opioid consumption was not demonstrated.
- *Patient Satisfaction.* Patients' global evaluation of study treatment (excellent plus good scores) significantly favored the OFIRMEV group over PCA morphine alone (40.8% vs. 23.1%,  $P = 0.004$ ). There were no differences between OFIRMEV and placebo groups in incidence of adverse events. No serious hepatic events were related to treatment with OFIRMEV 1 g. The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients

### Adult Pain Study 2, Cadence Study 304

This was a phase III, randomized, double-blind, placebo-controlled, multicenter, parallel-group, repeated-dose study of the analgesic efficacy and safety of OFIRMEV vs. placebo for the treatment of postoperative pain after abdominal laparoscopic surgery. A total of 244 patients received OFIRMEV 1 g or placebo Q6h, or OFIRMEV 650 mg or placebo Q4h. Opioid rescue medication was available to all patients.

- *Pain Intensity.* A significantly greater reduction in pain intensity differences from baseline was seen with OFIRMEV 1 g compared to the combined placebo group over the 24-hour period ( $P = 0.0068$ ). Time to meaningful pain relief after the first dose was significantly shorter in subjects who received OFIRMEV 1 g compared to the matched placebo group, with median values of 24.9 minutes and 53.9 minutes, respectively ( $P = 0.0028$ ). Similarly, there was a significant difference in pain intensity differences from baseline seen with OFIRMEV 650 mg compared with the combined placebo group over 24 hours ( $P = 0.0183$ ).
- *Morphine Consumption.* No statistical differences were found between OFIRMEV 1 g or 650 mg and the combined placebo groups in total rescue medication consumption or in the first time to rescue medication.
- *Patient Satisfaction.* Patient global evaluation of study treatment (excellent plus good scores) significantly favored OFIRMEV 1 g over the control group ( $P = 0.0004$ ).

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### Adult Fever Study 1, Cadence Study 302

This was a phase III, randomized, double-blind, placebo-controlled, single-center study that evaluated the antipyretic efficacy and safety of a single dose of OFIRMEV 1 g compared with placebo in 60 healthy adult males who developed fever induced by a standard dose of endotoxin.

- *Antipyretic Efficacy.* OFIRMEV 1 g was shown to be effective in blunting the peak temperature produced by endotoxin and reducing the fever it produced for a period of up to 6 h. The weighted sum of temperature differences over 6 hours (primary endpoint) was significantly better for OFIRMEV 1 g vs. placebo (P=0.0001). Importantly, OFIRMEV 1 g demonstrated a rapid onset of action and showed statistically significant temperature differences from baseline vs. placebo at T30 minutes (15 minutes after completing the infusion) (P=0.0085). Statistically significant reductions in temperature at each time point from 30 minutes through 5.5 hours were also observed for subjects who received OFIRMEV 1 g vs. placebo.

### **Post-Approval Commitments**

In accordance with a Pediatric Research Equity Act requirement included in the NDA approval of OFIRMEV, we will conduct a post-marketing efficacy study of OFIRMEV in infants and neonates. In addition, we plan to use the data from this study to satisfy a formal written request from the FDA under Section 505A of the U.S. Food, Drug and Cosmetic Act that was made as part of the approval process for OFIRMEV. The FDA has agreed to a due date for completion of this study in August 2015. Upon timely completion and the acceptance by the FDA of the data from this study, OFIRMEV will be eligible for an additional six months of marketing exclusivity.

### **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.

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### *Product Candidates*

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. We are aware of several third-party U.S. and Canadian patents and patent applications directed to various potential injectable formulations of acetaminophen, including intravenous formulations, as well as methods of making and using these potential formulations. 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.

### **Business Relationships**

#### ***Licensing Agreement with Bristol-Myers Squibb Company***

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 an additional \$15.0 million fee in November 2010 after approval of the product. In addition, we may be required to make future milestone payments totaling up to \$25.0 million upon the achievement of various milestones related to 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 the U.S. in 2021. 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.

***Option Agreement with Incline Therapeutics, Inc.***

Incline is developing IONSYS (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery. IONSYS is a compact, needle-free, self-contained, pre-programmed system designed to be applied to the skin on the upper arm or chest and activated by patients double clicking a button on the system. A generally imperceptible electrical current then actively delivers a small dose of the short-acting opioid analgesic fentanyl directly through the skin and into the systemic circulation. IONSYS was approved by both the FDA and the European Medicines Agency, or EMA, in 2006. The product was launched in Europe, but was withdrawn from the market by Incline's licensor in 2008 as a precautionary measure, and is not currently marketed anywhere in the world. Incline must obtain regulatory approval from the FDA for new patient safety features being developed into the system before it can market IONSYS in the U.S., and Incline must obtain regulatory approvals from comparable regulatory authorities before marketing IONSYS in other countries. Incline expects to submit a supplemental NDA to the FDA in 2013.

We believe that IONSYS is targeted to a large market opportunity with a significant unmet need. It is estimated that intravenous patient-controlled analgesia or IV PCA is used in approximately 40% to 50% of the more than 20 million inpatient procedures in the U.S. each year. IV PCA systems are controlled infusion pumps that deliver a prescribed amount of intravenous opioid when a patient activates a button connected to the device. IV PCA has become a leading method of treating acute post-operative pain in the hospital as it enables patients to self-administer opioids for the management of their pain. Patients who receive opioids by bolus injection may run a greater risk of receiving too much or too little opioid, both of which may have potential negative consequences for patients. Although IV PCA is typically the preferred approach for treating moderate to severe pain in the hospital, it may be associated with a number of potential drawbacks, including programming errors, medication errors, IV line infections, accidental needlestick injuries, significant hospital staff time and the need for maintenance, calibration, charging, sterilization and storage of pumps. We believe there is a significant unmet need to address such shortcomings. If we exercise our option to acquire Incline, we believe that IONSYS would be a strong commercial fit with OFIRMEV, if IONSYS is approved. Both OFIRMEV and IONSYS would primarily be marketed to anesthesiologists and surgeons. As a result, we expect that there would be a near 100% overlap with the call points for our sales force making it unlikely that we would need to add sales representatives in order to effectively promote IONSYS alongside OFIRMEV. We believe that the two products would be used in combination for the management of moderate to severe post-operative pain in hospitalized patients. This is consistent with most of our clinical trials of OFIRMEV in which opioids delivered using IV PCA were available for supplemental analgesia. If approved, we would expect that IONSYS would be used to replace IV PCA with transdermal PCA.

As consideration for the option, we paid Incline a \$3.5 million upfront option fee in June 2010 and made a second payment of \$3.5 million in September 2011 upon Incline's receipt of the second tranche of its Series A financing. We are currently in the second of two option periods, which extends until the earliest to occur of (1) 30 days after the date on which Incline submits a supplemental NDA for IONSYS to the FDA, (2) 30 days after the filing of an initial public offering by Incline, or (3) 42 months after the effective date of the option (December 21, 2013). During this second option period, we may acquire Incline for an amount not to exceed \$228.0 million plus payment of an additional amount not to exceed \$57.0 million upon FDA approval of IONSYS. We have an exclusive right of first negotiation to acquire Incline for the six-month period following the expiration of the second option period. In addition, we may elect to extend the second option period for two additional three-month periods upon the payment of \$2.5 million to Incline for each period. Incline will remain primarily responsible for the development of IONSYS. However, we and Incline have formed a joint development committee to oversee the global development and regulatory approval for the IONSYS product candidate.

***Development and Supply Agreement with Baxter Healthcare Corporation***

In January 2011, we entered into an amended and restated development and supply agreement with Baxter Healthcare Corporation, or Baxter, for the manufacture of OFIRMEV for commercial distribution by us in the U.S.

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Pursuant to the terms of the agreement with Baxter, we will pay Baxter a per unit purchase price based on the amount of finished OFIRMEV drug product produced, which price will be increased annually, and may be adjusted to reflect an increase or decrease, as the case may be, in the cost of material required to manufacture OFIRMEV, subject to specified limitations. We are obligated to purchase a minimum number of units of OFIRMEV each year or pay Baxter an amount equal to the purchase price multiplied by the shortfall in units. In addition, Baxter will be our primary supplier of OFIRMEV up to a specified number of units in each year, subject to Baxter's ability to timely supply the specified volumes required by us. However, if Baxter fails or declines to supply a sufficient quantity of OFIRMEV in accordance with our purchase orders during a specified period of time, then we may purchase that OFIRMEV from third party suppliers and such quantity will be deducted from the quantity of OFIRMEV that we otherwise would have been required to purchase from Baxter. We are also 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. We recorded a charge for the fourth quarter of 2011 and we placed certain finished product inventory of OFIRMEV on indefinite hold pending the outcome of an investigation into unidentified particulate matter observed during routine product stability testing. We decided to temporarily suspend further production by our primary supplier until the investigation has been completed and any necessary corrective and preventative actions have been implemented.

Under the agreement with Baxter, we and Baxter agreed to complete a capacity increase development plan for the expansion of the manufacturing capacity for OFIRMEV at Baxter's facilities. All capital equipment and facility improvements included in the plan will be funded by us. We will not be able to reasonably estimate the cost of expansion until the capacity increase development plan has been completed.

The initial term of the agreement with Baxter will terminate on November 1, 2015, and will automatically renew for successive one-year periods thereafter, unless either party provides at least two years prior written notice of termination to the other party. In addition, either party may terminate the agreement (1) within 90 days, after written notice in the event of a material uncured breach of the agreement by the other party or (2) immediately, upon the filing of a petition of bankruptcy by the other party. We may also terminate the agreement, effective 30 days after providing written notice, in the event that Baxter does not agree to the assignment of the agreement by us to a competitor of Baxter. Baxter has agreed that, for the initial term and any renewals or extensions of the agreement, neither it nor any of its affiliates will develop or commercially produce, for itself or for any third party, any intravenous formulation of a product containing acetaminophen for distribution or sale in the U.S.

If the agreement with Baxter is terminated, except as a result of a material uncured breach or bankruptcy by Baxter, we will reimburse Baxter for all materials ordered prior to the termination of the agreement that are not cancelable at no cost to Baxter. Upon termination of the agreement and subject to certain exceptions, we will purchase from Baxter all undelivered products manufactured or packaged under a purchase order from us, at the price in effect at the time the purchase order was placed. We are also obligated to reimburse Baxter for reasonable costs incurred in returning all Cadence-owned equipment and for restoring Baxter's manufacturing facility to its condition prior to the installation of OFIRMEV-related improvements, other than restoration costs for changes that Baxter reasonably agrees are usable by Baxter at the time of removal of the Cadence-owned equipment. We are 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.

### ***Supply Agreement with Lawrence Laboratories, Inc.***

In addition, in December 2010, we entered into an agreement with Lawrence Laboratories, an indirect wholly-owned subsidiary of BMS, to be a supplemental source for OFIRMEV. Bristol-Myers Squibb Srl, or BMS Anagni, an indirect subsidiary of BMS located in Anagni, Italy, will manufacture OFIRMEV on behalf of Lawrence Laboratories. BMS Anagni also currently manufactures intravenous acetaminophen for sale and distribution by BMS and its affiliates in a number of countries outside of the U.S. and Canada. The FDA

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approved the BMS Anagni facility as an additional manufacturing site for OFIRMEV in March 2011. We believe that the geographic diversification of our manufacturing operations afforded by the arrangement with Lawrence Laboratories supports our corporate risk management objectives.

### ***Distribution and Wholesaler Agreements***

We distribute OFIRMEV primarily to drug wholesalers, who in turn 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 have entered into agreements with the major pharmaceutical wholesalers for distribution management services and data reporting in exchange for a fee.

### **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 2,233,924), or the '222 patent, covers the formulation of OFIRMEV and formulations made by that process and expires in August 2017. U.S. Patent No. 6,992,218 (Canadian patent application 2,415,403), or the '218 patent, covers the process used to manufacture OFIRMEV and expires in June 2021. We plan to complete a pediatric clinical trial by August 2015 and, upon timely completion and the acceptance by the FDA of the data from this study, OFIRMEV will be eligible for an additional six months of marketing exclusivity.

### ***OFIRMEV and Pending Litigation***

In August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock Laboratories, Inc., Perrigo Company and Paddock Laboratories, LLC, collectively referred to herein as Paddock, and against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc., collectively referred to herein as Exela. The lawsuit follows the notices that we received in July 2011 from each of Paddock and Exela concerning their filings of Abbreviated New Drug Applications, or ANDAs, containing a "Paragraph IV" patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit, we allege that Paddock and Exela have each infringed the '222 patent and the '218 patent by filing their respective ANDAs seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The '222 and the '218 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA until the earlier of the expiration of a 30-month period, the expiration of the '222 and '218 patents, the entry of a settlement order or consent decree stating that the '222 and '218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Paddock or Exela, or such shorter or longer period as the Court may order. Each of Paddock and Exela has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed counterclaims. A date for the bench trial in this case has been tentatively scheduled for May 2013.

Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. Specifically, the FDA has granted OFIRMEV three years of regulatory exclusivity, which expires November 2, 2013. We intend to vigorously enforce our intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of our patents. The '222 patent expires August 5, 2017 (or February 5, 2018 if pediatric exclusivity is granted) and the '218 patent expires June 6, 2021 (or December 21, 2021 if pediatric exclusivity is granted). However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or any other litigation. Regardless of how this litigation is ultimately resolved, this matter may be costly, time-consuming and distracting to our management, which could have a material adverse effect on our business.



## **Research and Development**

Our research and development expenses were \$8.9 million in 2011, \$13.8 million in 2010 and \$19.5 million in 2009. Our historical research and development expenses relate predominantly to OFIRMEV and our discontinued omiganan pentahydrochloride product candidate. Our research and development expenses consist primarily of salaries and related employee benefits for our research and development team, license fees paid to our licensors prior to approval of our drug candidates, pre-commercialization manufacturing development activities, costs associated with clinical trials, and costs associated with non-clinical activities, such as expenses related to regulatory submissions. 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. The clinical trial expenses include payments to vendors such as clinical research organizations and investigator sites, clinical suppliers and related consultants.

We expect to continue to incur research and development expenses related to OFIRMEV, however, it is difficult to anticipate the scope and magnitude of our future research and development expenses. For example, the FDA has required that we complete a post-approval clinical trial for OFIRMEV in pediatric patients under two years of age, and has agreed to a due date for completion of this study in August 2015. We may also conduct clinical studies to expand the indications for OFIRMEV. 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.

## **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.

## **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.

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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 the Prescription Drug User Fee Act, or 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 Act. 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 Act permits 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

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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 earlier of the expiration of a 30-month period, the expiration of the patent, the entry of a settlement order or consent decree stating that the patent are invalid or not infringed, a decision in the case concerning infringement or validity 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. The Hatch-Waxman Act 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 the Hatch-Waxman Act 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 such as we filed for OFIRMEV, 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**

### ***FDA Post-Approval Regulatory Requirements***

We may also be subject to a number of post-approval regulatory requirements. For example, in accordance with a Pediatric Research Equity Act requirement included in the NDA approval of OFIRMEV, we will conduct a post-marketing efficacy study of OFIRMEV in infants and neonates. In addition, we plan to use the data from this study to satisfy a formal written request from the FDA under Section 505A of the U.S. Food, Drug and Cosmetic Act that was made as part of the approval process for OFIRMEV. The FDA has agreed to a due date for completion of this study in August 2015. 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, 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.

### ***Other Government Regulatory Requirements***

In addition to FDA restrictions on marketing of pharmaceutical products, we are subject to various state and federal laws pertaining to healthcare "fraud and abuse," including anti-kickback statutes and false claims statutes. The federal 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.

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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, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, imposes new reporting and disclosure requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals. Although there is some uncertainty as to the exact extent of the requirements and definitive guidance has not yet been provided by the government, it is currently anticipated that data capture to comply with the new requirements will need to begin in late 2012, with reporting requirements effective in 2013. In addition, pharmaceutical and device manufacturers will also be required to report and disclose investment interests in such companies (other than publicly traded securities) held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties for payments, transfers of value or ownership or investment interests not reported in an annual submission. Additionally, if not preempted by this federal law, several states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing various other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, certain states require pharmaceutical companies to implement compliance programs or marketing codes. Currently, several additional states are considering similar proposals. Companies must also be registered or licensed by the federal and state governments prior to manufacturing or distributing prescription drug products.

We also make our products available to authorized users of the Federal Supply Schedule, or FSS, of the General Services Administration. As a result of the Veterans Health Care Act of 1992, or the VHC Act, federal law requires that we offer deeply discounted FSS contract pricing for purchases by the Department of Veterans Affairs, the Department of Defense, the Coast Guard and the Public Health Service, including the Indian Health Service, in order for federal funding to be available for these four federal agencies and certain federal grantees to purchase our products. FSS pricing to these four federal agencies must be equal to or less than the Federal Ceiling Price, or FCP, which is 24% below the Non-Federal Average Manufacturer Price, or Non-FAMP, for the prior fiscal year. The accuracy of the pricing and other information we report may be audited by the government under applicable federal procurement laws and the terms of our FSS contract. Among the remedies available to the government for inaccuracies in our pricing information is recoupment of any overcharges resulting from such inaccuracies and civil monetary penalties of \$100,000 per item that is incorrect.

We and our contract 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.

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Additionally, the U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA would include interactions with certain healthcare professionals in many countries. Our present and future business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

### **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 March 1, 2012, we had approximately 220 employees.

**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. You should carefully consider the risks described below, in addition to the other information contained in this report, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.*

**Risks Related to Our Business and Industry**

***Our success depends on our ability to successfully commercialize our only product, OFIRMEV®.***

Our success depends on our ability to effectively commercialize our only product, OFIRMEV, which was approved by the FDA in November 2010 for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever in adults and children two years of age and older.

We launched OFIRMEV in January 2011, but our ability to effectively commercialize and generate revenues from OFIRMEV will depend on several factors, including:

- our ability to create market demand for OFIRMEV through our own marketing and sales activities, and any other arrangements to promote this product we may later establish;
- our ability to train, deploy and support a qualified sales force;
- our ability to secure formulary approvals for OFIRMEV at a substantial number of targeted hospitals;
- our ability to maintain and defend our patent protection and regulatory exclusivity for OFIRMEV;
- our ability to procure a supply of OFIRMEV from our third-party manufacturers in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;
- the performance of our third-party manufacturers and our ability to ensure that our supply chain for OFIRMEV efficiently and consistently delivers OFIRMEV to our customers;
- our ability to implement and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- the occurrence of adverse side effects or inadequate therapeutic efficacy of OFIRMEV, and any resulting product liability claims or product recalls; and
- the availability of adequate levels of reimbursement coverage for OFIRMEV from third-party payors.

Any disruption in our ability to generate revenues from the sale of OFIRMEV or lack of success in its commercialization will have a substantial adverse impact on our results of operations.

***Our efforts to successfully commercialize OFIRMEV are subject to many internal and external challenges and if we cannot overcome these challenges in a timely manner, our future revenues and profits could be materially and adversely impacted.***

OFIRMEV was launched in January 2011. Since that time, we have continued to expend significant time and resources to train our sales force to be credible and persuasive in discussing OFIRMEV with physicians, nurses, hospitals and other customers, and to ensure that a consistent and appropriate message about OFIRMEV is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential

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customers about the benefits and risks of OFIRMEV and its proper administration, our efforts to successfully commercialize OFIRMEV could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

In addition to extensive internal efforts, the successful commercialization of OFIRMEV requires many third parties, over whom we have no control, to decide to utilize OFIRMEV. These third parties include physicians, pharmacists, and hospital pharmacy and therapeutics committees, or P&T committees. Generally, before we can attempt to sell OFIRMEV in a hospital, OFIRMEV must be approved for addition to that hospital's list of approved drugs, or formulary list, by the hospital's P&T committee. A hospital's P&T committee typically governs all matters pertaining to the use of medications within the institution, including review of medication formulary data and recommendations for the appropriate use of drugs within the institution to the medical staff. The frequency of P&T committee meetings at various hospitals varies considerably, and P&T committees often require additional information to aide in their decision-making process, so we may experience substantial delays in obtaining formulary approvals. Additionally, hospital pharmacists may be concerned that the cost of acquiring OFIRMEV for use in their institutions will adversely impact their overall pharmacy budgets, which could cause pharmacists to resist efforts to add OFIRMEV to the formulary, or to implement restrictions on the usage of the drug in order to control costs. We cannot guarantee that we will be successful in getting the approvals we need from enough P&T committees and overcoming any financial objections raised by hospital pharmacists quickly enough to optimize hospital sales of OFIRMEV.

Even if we obtain hospital formulary approval for OFIRMEV, physicians must still prescribe OFIRMEV for its commercialization to be successful. Because OFIRMEV is a relatively new drug with no track record of sales in the U.S. prior to January 2011, any inability to timely supply OFIRMEV to our customers, or any unexpected side effects that develop from use of the drug, may lead physicians to not accept OFIRMEV as a viable treatment alternative.

***We may require substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate some or all of our planned activities.***

We began generating revenue from the launch of OFIRMEV in January 2011, however, we expect our negative cash flow from operations to continue until we are able to generate significant revenues from sales of OFIRMEV. As a result, we may need to raise additional capital to:

- fund our operations as we implement our marketing strategies, establish and maintain our sales force and commercial infrastructure and commercialize OFIRMEV;
- purchase sufficient quantities of OFIRMEV from our contract manufacturers to meet customer demand or our minimum purchase obligations;
- continue to fund the expansion of our contract manufacturers' capacity to produce OFIRMEV in order to meet future demand for this product;
- complete one or more efficacy, pharmacokinetic and pharmacodynamic studies of OFIRMEV in pediatric patients under two years of age, as required to comply with our post-commercialization commitment to the FDA;
- exercise our option to acquire Incline; or
- acquire or in-license other products, businesses or technologies that we believe are a strategic fit.

Our funding requirements related to the commercialization of OFIRMEV may exceed our current projections as a result of many factors, including, but not limited to:

- our sales of OFIRMEV may be lower than expected;
- the costs associated with our efforts to sell, market and distribute OFIRMEV, including costs associated with establishing and maintaining our sales force and commercial infrastructure, may be greater than anticipated;



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- we may incur unexpected costs in order to ensure a sufficient supply of OFIRMEV from our contract manufacturers in order to meet customer demand, including any replacement of product or write down of inventory related to any product recall or other quality issue, or we may be required to pay fees based on minimum purchase obligations; and
- we may be required to file lawsuits to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of intravenous acetaminophen, such as our Paragraph IV litigation, including any such costs we may be required to expend if our licensors are unwilling or unable to do so.

Until we can generate a sufficient amount of revenue from sales of OFIRMEV, 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 have engaged in various financing activities in the past. In May 2011, for example, we established a universal shelf registration statement to permit us, from time to time, to offer and sell up to \$150.0 million of equity or debt securities. In November 2011, we undertook a public offering of common stock using our universal shelf registration statement that raised net proceeds of approximately \$77.3 million. In addition, in December 2011, we refinanced our \$30.0 million secured credit facility with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation. However, there can be no assurance in the future that we would be able to enter into similar financing arrangements or complete any securities offerings, including under our universal shelf registration statement, and to the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted.

We believe we have sufficient financial resources to fund our projected operating requirements, at a minimum, for the next twelve months. This estimate does not reflect any exercise of our right to acquire Incline or participation in other strategic transactions. 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. 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 reduce the scope of or eliminate some or all of our sales, marketing and commercialization efforts for OFIRMEV, or we may not be able to adequately fund our Paragraph IV litigation, which could decrease sales of this product and have a material adverse effect on our financial condition, stock price and operations.

***We have no manufacturing capabilities and depend entirely upon our contract manufacturers to produce OFIRMEV. If our contract manufacturers fail to meet our requirements for OFIRMEV, or fail to fully comply with cGMP regulations, we may 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 no such manufacturing capabilities, so we have relied upon Baxter Healthcare Corporation, or Baxter, as our primary source for OFIRMEV.

Following the commercial launch of OFIRMEV, we amended our long-term development and supply agreement with Baxter in January 2011. In order to meet anticipated demand for OFIRMEV, 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. Major components of this processing equipment are currently available from single sources, and if this equipment is not delivered on time or at all, the manufacturing capacity for OFIRMEV may not keep pace with anticipated demand. Any termination or disruption of our relationship with Baxter may materially harm our business and financial condition, and adversely impact our commercialization and sales efforts with respect to OFIRMEV.

In addition, in December 2010, we entered into an agreement with Lawrence Laboratories, an indirect wholly-owned subsidiary of BMS, to be a supplemental source for OFIRMEV. Bristol-Myers Squibb Srl, or

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BMS Anagni, an indirect subsidiary of BMS located in Anagni, Italy, will manufacture OFIRMEV on behalf of Lawrence Laboratories. BMS Anagni also currently manufactures intravenous acetaminophen for sale and distribution by BMS and its affiliates in a number of countries outside of the U.S. and Canada. The FDA approved the BMS Anagni facility as an additional manufacturing site for OFIRMEV in March 2011.

Baxter and Lawrence Laboratories must comply with strictly enforced federal, state and foreign regulations, including GMP regulations. The FDA will re-inspect our third party manufacturers' facilities from time to time and, in the event that any such inspection reveals that either facility is not in compliance with applicable regulations, the FDA may issue fines and civil penalties, suspend production, suspend or delay any subsequent product approvals, seize or recall our products, or withdraw our product approval, which would limit the availability of OFIRMEV. 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 our relationships with our customers, product liability claims and litigation.

We also currently rely upon a single source for the manufacture of the active pharmaceutical ingredient, or API, for OFIRMEV, as well as for other critical components of OFIRMEV. We have entered into a supply agreement for the commercial supply of the API. If our supplier becomes unable to meet our demand for the API, the process of changing or adding a new API manufacturer may require additional testing and prior FDA approval and may be expensive and time-consuming. If we were unable to manage such changes effectively, we could face supply disruptions that could result in significant costs and delays, damage to our reputation or commercial prospects and cause us to lose potential revenues.

Although we actively manage these third party relationships to ensure continuity and quality, some events beyond our control could result in the complete or partial failure of these goods and services. Any such failure could have a material adverse effect on our financial condition and operations. In addition, as OFIRMEV is a new product, the effect of any delay or failure to deliver could be magnified due to the lack of a sales track record for OFIRMEV in the U.S. For example, in February 2012, we announced a voluntary recall of a single lot of OFIRMEV due to the presence of an unidentified, visible particle in one vial of that lot during routine stability testing. Some of our customers experienced short-term supply delays due to the temporary suspension of shipments from the supplier of the affected lot before we were able to accelerate shipments of OFIRMEV from our other supplier. In addition, we recorded a charge of \$5.6 million for the fourth quarter of 2011 and placed certain finished product inventory of OFIRMEV on indefinite hold pending the outcome of an investigation into unidentified particulate matter observed during routine product stability testing. The charge was recorded due to uncertainty as to the amount of time that may be required to complete the investigation and whether the product will have sufficient remaining shelf life or otherwise be saleable after the investigation is completed. We decided to temporarily suspend further production by our primary supplier until the investigation has been completed and any necessary corrective and preventative actions have been implemented. This recall, the investigation and any future recall or investigation that we may experience could negatively affect customer perceptions and reduce revenue from OFIRMEV, and could also result in unexpected costs for replacement product, investigational costs and the write down of inventory.

***We have never marketed a drug prior to OFIRMEV, and if we are unable to maintain an effective commercial infrastructure, we will not be able to successfully commercialize OFIRMEV.***

We have built our own sales and marketing capabilities in order to market OFIRMEV directly to physicians, nurses, hospitals, group purchasing organizations and other customers, and will continue to incur significant expenses associated with the recruitment, training and compensation of our sales representatives. The continued development of our hospital-focused sales, marketing and distribution infrastructure for our domestic operations will be expensive and time consuming, and there may be unforeseen costs and expenses or time-delays associated with such activities. If we are not successful in training and managing our sales and marketing personnel, we may not achieve our sales objectives. In addition, if we are unable to establish and maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue, may experience increased expenses, and may never become profitable.

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***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 will continue to face competition in our efforts to market and sell OFIRMEV from other 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 injectable 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 NSAID, is also available generically in the U.S. from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, is available 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 our in-licensed patent rights. 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. In August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock and Exela alleging that each has infringed the '222 and '218 patents, which are listed in the Orange Book for OFIRMEV, by filing their respective ANDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA. Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. We intend to vigorously enforce our intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of our patents. However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or guarantee the outcome of any litigation. In addition, we are aware of several third-party U.S. and Canadian patents and patent applications directed to various potential injectable formulations of acetaminophen, including intravenous formulations, as well as methods of making and using these potential formulations. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research 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 be able to obtain patent protection or other intellectual property rights that limit our ability to 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 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 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;
- 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 reasonable cost, achieve hospital formulary acceptance for the product and sell the product at a competitive price, 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 OFIRMEV and any other product candidate to hospitals that are members of 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 OFIRMEV and any other product candidates we may license or acquire. If OFIRMEV, or any other product candidate that is approved, does 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 and risks of OFIRMEV or any other product candidates may require significant resources and may never be successful.

***We rely on third parties to perform many essential services for OFIRMEV and any other 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 efforts to commercialize OFIRMEV or any other products may be significantly impacted and we may be subject to regulatory sanctions.***

We rely on third-party service providers to perform a variety of functions related to the sale and distribution of OFIRMEV, key aspects of which are out of our direct control. The services provided by these third parties include warehousing and inventory control, distribution, customer service, accounts receivable management and cash collection. As a result, most of our inventory is stored at a single warehouse maintained by one such service provider. 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 if our products 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 OFIRMEV and related services. If the quality or accuracy of the data maintained or services performed by these third parties is insufficient, we could be subject to regulatory sanctions.

***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:

- decreased demand for OFIRMEV or other product candidates;
- loss of revenues;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- withdrawal of clinical trial participants;
- significant distraction of our scientific and management personnel who may be involved in our efforts to defend against such claims; and
- the inability or lack of commercial rationale to continue commercialization of OFIRMEV or any other product candidates.

Although we currently have commercial product liability coverage for OFIRMEV, which includes coverage for any clinical trials we may perform, insurance coverage is becoming increasingly expensive and we may be unable to obtain commercially reasonable product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. Our commercial product liability insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. 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.

***Although OFIRMEV has received regulatory approval from the FDA, it remains subject to substantial, ongoing regulatory requirements.***

OFIRMEV remains subject to ongoing FDA requirements with respect to manufacturing, labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. The FDA has the authority to regulate the claims we make in marketing OFIRMEV to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the approved label for the drug. In addition, the discovery of previously unknown problems with OFIRMEV, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, may result in the imposition of additional restrictions, including withdrawal of the product from the market.

For example, as a condition of the approval of OFIRMEV, we are required to complete one or more efficacy, pharmacokinetic and pharmacodynamic studies of OFIRMEV in pediatric patients under two years of age, and to submit the final results of this clinical trial to the FDA. Depending on the outcome of this study, we may be unable to expand the indications for OFIRMEV or we may be required to include specific warnings or limitations on dosing this product, which could negatively impact our sales of OFIRMEV.

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We have implemented a comprehensive compliance program and related infrastructure, but we cannot provide absolute assurance that we are or will be in compliance with all potentially applicable laws and regulations. If our operations in relation to OFIRMEV fail to comply with applicable regulatory requirements, the FDA or other regulatory agencies may:

- issue warning letters or untitled letters;
- impose consent decrees, which may include the 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;
- exclude us from participating in U.S. federal healthcare programs, including Medicaid or Medicare; 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. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments, and such off-label uses by healthcare professionals are common. 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.

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

In March 2010, the President signed the Patient Protection and Affordable Care Act, or PPACA, which makes extensive changes to the delivery of health care in the U.S. The PPACA includes numerous provisions that affect pharmaceutical companies, some of which became effective immediately and others of which will be taking effect over the next several years. For example, the PPACA seeks to expand health care coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA will also impose substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit, an annual fee imposed on all manufacturers of brand prescription drugs in the U.S., and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The PPACA also contains cost containment measures that could reduce reimbursement levels for health care items and services generally, including pharmaceuticals. It also will require reporting and public disclosure of payments and other transfers of value provided by pharmaceutical companies to physicians and teaching hospitals. We cannot predict what effect the PPACA or other healthcare reform initiatives that may be adopted in the future will have on our business. Several lawsuits have been filed challenging the constitutionality of provisions of the PPACA, with varying results. Although it is possible that all or portions of the PPACA may be repealed or determined to be unconstitutional, other health reform legislation may be implemented. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts. Although there is some uncertainty as to the exact extent of the requirements and definitive guidance has not yet been provided by the government, it is currently anticipated that data capture to comply with the new requirements will need to begin in late 2012, with reporting requirements effective in 2013. In addition, pharmaceutical and device manufacturers will also be required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties for payments, transfers of value or ownership or investment interests not reported in an annual submission. Compliance with the PPACA and state laws with similar provisions is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. 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, results of operations and growth prospects.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. 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 2015. Compliance with California and future federal or state electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens. 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.

Managed care organizations are increasingly challenging the prices charged for medical products and services and, in some cases, imposing restrictions on the coverage of particular drugs. Many managed care organizations negotiate the price of medical services and products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's patient population. The process for obtaining coverage can be lengthy and costly, and we expect that it could take several months before a particular payor initially reviews our product and makes a decision with respect to coverage. For example, third-party payors may require cost-benefit analysis data from us in order to demonstrate the cost-effectiveness of OFIRMEV or any other product we might bring to market. For any individual third-party payor, we may not be able to provide data sufficient to gain reimbursement on a similar or preferred basis to competitive products, or at all.

***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 outside of the U.S. to commercialize OFIRMEV or any other product candidates we may acquire.***

Our rights to OFIRMEV include Canada, as well as the U.S. In order to market OFIRMEV and any other 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, clinical 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. For example, we are currently evaluating the commercial prospects, partnering opportunities and feasibility of applying for marketing authorization for OFIRMEV in Canada, and we anticipate that the product would not be approved by Canadian regulatory authorities for at least 18 months after the date on which any such application is submitted, if at all. 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



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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 OFIRMEV and any other 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 result in new requirements from regulatory agencies to include 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. For example, in January 2011, the FDA issued a press release and posted on its website a drug safety communication asking manufacturers of prescription drug products containing combinations of acetaminophen and opioid medications to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each dosage unit (i.e. each tablet or caplet). In the announcement, the FDA also requested manufacturers to update labels for such products to include a boxed warning highlighting the potential for severe acetaminophen-induced liver injury and a warning highlighting the potential for allergic reactions. The boxed warning required for affected products reaffirms previous statements made by the FDA that most cases of liver injury are associated with acetaminophen doses that exceed 4,000 mg per day. While the FDA has indicated that this communication does not apply to intravenous acetaminophen, it is possible that the FDA may apply similar labeling requirements to OFIRMEV in the future.

We reaffirmed our dosing recommendations for OFIRMEV in July 2011 following a news release by a major manufacturer of over-the-counter acetaminophen products announcing its plan to lower the recommended maximum daily dose of some oral acetaminophen products in an effort to reduce the risk of accidental acetaminophen overdose among its customers in the over-the-counter setting. Also, the California “State’s Experts” acting under Proposition 65 have recommended a high priority for a review of acetaminophen by the Office of Environmental Health Hazard Assessment, which, depending on subsequent research and findings, could lead to the requirement for a warning statement to be added to the label for over-the-counter acetaminophen products that such products contain chemicals known to the State of California to cause cancer. We believe that OFIRMEV, like other prescription products, would be exempt from this additional labeling requirement. However, any perception or concern that acetaminophen is unsafe could harm our ability to successfully commercialize and sell OFIRMEV, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, granted 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 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 that law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. 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 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 anticipated sales of OFIRMEV or 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. In addition, some third-party payors are emphasizing the substitution of branded pharmaceuticals with less expensive generic equivalents. An increase in the sales of generic pharmaceutical products could result in a decrease in revenues of branded pharmaceuticals. While there are no generic equivalents competing with OFIRMEV at this time, in the future we could face generic competition. In August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock and Exela alleging that each has infringed the '222 and '218 patents, which are listed in the Orange Book for OFIRMEV, by filing their respective ANDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA. Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. We intend to vigorously enforce our intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of our patents. However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or guarantee the outcome of any litigation.

OFIRMEV or any other product candidates that we may in-license or acquire, if approved, will face competition from other therapies and drugs, as well as other routes of administration of acetaminophen, 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 twelve 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 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 OFIRMEV or any other 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 commercialize OFIRMEV.***

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 continue to 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 OFIRMEV and may lead to a complete termination of our related commercialization efforts.

***If BMS breaches the underlying agreement under which we sublicense the rights to OFIRMEV, we could lose the ability to commercialize OFIRMEV.***

Our license for OFIRMEV is subject to the terms and conditions of a license from 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 Pharmatop, and neither BMS nor we adequately cure that breach, or BMS and Pharmatop otherwise become involved in a dispute, the breach by BMS or disputes with 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 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 Pharmatop to BMS could result in our loss of exclusive rights to OFIRMEV and may lead to a complete termination of our commercialization efforts for OFIRMEV.

***We may experience difficulties in managing the growth of our organization.***

As of March 1, 2012, we had approximately 220 employees. The commercial launch of OFIRMEV in January 2011 required us to substantially expand our managerial, commercial, financial and other personnel resources, particularly in sales and marketing positions. Additionally, beginning in November 2011, we implemented a reduction in force of 17 employees, or approximately 7% of our total work force at that time, primarily in our development and general and administrative areas. This action was taken in order to focus our resources on commercialization activities for OFIRMEV and to reduce programmatic costs not directly associated with such efforts. Despite these efforts, our management, personnel, systems and facilities currently in place may not be adequate to support our commercially-focused organization, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses. 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:

- effectively train and manage our employees, and establish appropriate systems, policies and infrastructure to support our 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 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.

***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. 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 our operations may be setback.

***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.***

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. For example, we signed an agreement in June 2010 granting us an option to acquire Incline. As part of our efforts to acquire businesses such as Incline, or to in-license products, we conduct technical, business and legal due diligence with the goal of identifying and evaluating material risks involved in such transactions, which may include:

- 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;

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- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- effectiveness of the acquired business's internal controls and procedures;
- 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.

Additionally, in connection with any such acquisition or in-licensing transaction, we must estimate the value of the transaction by making certain assumptions about, among other things, likelihood of regulatory approval for unapproved products and the market potential for marketed products and/or product candidates. Ultimately, our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of a transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, we might not realize the intended advantages of the acquisition or in-licensing transaction. If we fail to realize the expected benefits from the transactions we have consummated or may consummate in the future, the results of our operations and financial condition could be adversely affected.

It cannot be assured that, following an acquisition, we will achieve revenues, specific net income or loss levels that justify the acquisition or that the acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or private debt or equity financings to acquire any businesses, which would result in dilution for stockholders or the incurrence of indebtedness. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

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.

***We may not be able to exercise our option to acquire Incline and, even if we are able to, we may fail to realize the anticipated benefits of the transaction.***

We signed an agreement in June 2010 granting us the option to acquire Incline, but we may not have sufficient capital to exercise this option. We are currently in the second of two option periods under this agreement, and if we elect to exercise the option, the payment of up to \$228.0 million, plus up to \$57.0 million upon FDA approval of IONSYS, would require us to raise additional funds to finance the acquisition. Raising such additional funds or paying up to 50% of the applicable option exercise payment in the form of our common stock would result in the incurrence of additional indebtedness or dilution for our stockholders.

We are relying on Incline to develop and obtain regulatory approval for IONSYS. Although Theodore R. Schroeder, our President and CEO, serves as our representative on Incline's board of directors, and we have formed a joint development committee to oversee the global development of, and pursuit of regulatory approval for, IONSYS, Incline will remain responsible for these activities unless and until we elect to acquire Incline. We do not control these development activities and therefore cannot be certain that they will be accomplished in a satisfactory manner. For example, Incline may breach one of the agreements under which it has licensed the rights to IONSYS, and lose the ability to continue to develop and commercialize this product candidate. In addition, Incline's efforts to develop improved patient safety features for IONSYS may be unsuccessful, or Incline may not develop a risk evaluation and management strategy, or REMS, for IONSYS that is acceptable to the FDA. Even if a REMS for IONSYS is approved by the FDA, the implementation of any such strategy may not be commercially feasible.

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If we elect to acquire Incline, there will be a number of risks involved in the acquisition, including the potential for our management's attention to be diverted from, or for disruptions to affect, our ongoing business, and difficulties and expenses related to integrating the acquired business and retaining all or part of its personnel. In addition, there is the risk that our valuation assumptions for Incline may turn out to be erroneous or inappropriate, which could result in our having overvalued Incline, or that the contemplated benefits of acquiring Incline do not materialize as planned. We cannot assure you that, if we acquire Incline, the acquisition will result in increased earnings or reduced losses for the combined company in any future period. The individual or combined effects of these risks could have a material adverse effect on our business.

***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 OFIRMEV 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.

### **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 is not available for the acetaminophen molecule itself in the territories licensed to us, which include the U.S. and Canada. 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, Pharmatop. We are the exclusive licensee of two U.S. patents and two issued Canadian patent and one pending Canadian patent application owned by Pharmatop, under BMS's license to these patents from Pharmatop. U.S. Patent No. 6,028,222 (Canadian patent application number 2,233,924) covers the formulation of OFIRMEV, and this patent expires in August 2017. U.S. Patent No. 6,992,218 (Canadian patent number 2,415,403) covers the process used to manufacture OFIRMEV, and this patent expires in June 2021. We plan to complete a pediatric clinical trial by August 2015 and, upon timely completion and the acceptance by the FDA of the data from this study, OFIRMEV will be eligible for an additional six months of marketing exclusivity.

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 directed to 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 directed to 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. The commercial opportunity for OFIRMEV could be significantly harmed if competitors are able to develop alternative formulations of acetaminophen outside the scope of our in-licensed patents.

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Two third-parties have challenged, and additional third parties may challenge the patents covering OFIRMEV, 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 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, in the opinion of that third party, the patent listed in the Orange Book for a branded product is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the third party's generic drug product. A third party 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 patent certification. If the third party submits a Paragraph IV patent certification to the FDA, a notice of the Paragraph IV patent certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. A lawsuit may then be initiated to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of the receipt of notice of a Paragraph IV patent certification automatically prevents the FDA from approving the ANDA until the earlier of the expiration of a 30-month period, the expiration of the patents, the entry of a settlement order stating that the patents are invalid or not infringed, a decision in the infringement case that is favorable to the ANDA applicant, or such shorter or longer period as the court may order. If a patent infringement lawsuit is not initiated within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay.

In August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock and Exela alleging that each has infringed the '222 and '218 patents, which are listed in the Orange Book for OFIRMEV, by filing their respective ANDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA. Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. We intend to vigorously enforce our intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of our patents. However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or guarantee the outcome of any litigation.

Certain pharmaceutical companies' patent settlement agreements with generic pharmaceutical companies have been challenged by the U.S. Federal Trade Commission alleging a violation of Section 5(a) of the Federal Trade Commission Act, and any patent settlement agreement that we may enter into with any generic pharmaceutical company may be subject to similar challenges, which could be both expensive and time consuming and may render such settlement agreements unenforceable.

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. Any adverse outcome of such litigation could result in one or more generic versions of OFIRMEV being launched before the expiration of the patents we have in-licensed from BMS and its licensor, Pharmatop, which could adversely affect our ability to successfully execute our business strategy to increase sales of OFIRMEV and negatively impact our financial condition and results of operations.

***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 devote 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, 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 Pharmatop devote on our behalf, or the priority they place on maintaining and enforcing our patent rights, and prosecuting patent applications to our advantage.

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Pharmatop is under a contractual obligation to BMS to maintain the issued OFIRMEV patents in the U.S., and to diligently prosecute the patent applications and maintain any issued patents related to OFIRMEV in Canada. BMS has the opportunity to consult, review and comment on any patent office communications. We may not receive any patent from the applications in Canada, or if patents are issued they may be inadequate to protect our OFIRMEV product from competition.

For a third-party challenge to the validity or enforceability of the OFIRMEV patents, we will have some ability to participate in either Pharmatop's or BMS' defense thereof. In the event that neither Pharmatop nor BMS elects to defend the third-party challenge, we may have the opportunity to defend it. BMS has the first right to prosecute a third-party infringement of the OFIRMEV patents relating to OFIRMEV, and Pharmatop has the second right. We may not have the ability to cooperate with BMS or Pharmatop in any such third-party infringement suits. In certain instances, we may be allowed to pursue a third-party infringement claim ourselves.

It is possible that Pharmatop or BMS could take some action or fail to take some action that could harm the patents related to OFIRMEV. For example, if Pharmatop decides it no longer wants to maintain the OFIRMEV patents, to prosecute the patent applications related to OFIRMEV in Canada, or if Pharmatop or BMS decide not to defend the patents against third party challenges, we risk losing the benefit of all or some of those patent rights. Moreover, Pharmatop or BMS may experience serious difficulties related to their respective businesses or financial stability, and may be unwilling or unable to continue to expend the financial resources required to maintain and prosecute these patents and patent applications, or to defend the patents against third party challenges.

Our success will depend in part on our ability to obtain and maintain patent protection for OFIRMEV, both in the U.S. and Canada. While we intend to take actions reasonably necessary to enforce our patent rights, we depend on our licensors to protect a substantial portion of our 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.

We or our licensors may also be notified of alleged infringement and be sued for infringement of third-party patents or other proprietary rights. 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. 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.



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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.

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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 began generating revenues from the commercialization of OFIRMEV in January 2011. Prior to that time, we 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 \$93.0 million, \$56.6 million and \$45.5 million for the years ended December 31, 2011, 2010 and 2009, respectively. As of December 31, 2011, we had an accumulated deficit of \$366.7 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and our working capital. For example, while our development expenses decreased in 2011 and 2010 due to the completion of our clinical development program for OFIRMEV, and the discontinuation of our development program for our omiganan pentahydrochloride product candidate, we incurred increased commercialization and marketing expenses during 2011 and 2010 as we launched OFIRMEV. Further, in 2011, we also incurred significant increased sales, marketing and outsourced manufacturing expenses. In addition, we are required to pay a minimum annual royalty

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under our license agreement for OFIRMEV and we have minimum purchase obligations under our supply agreements with our contract manufacturers for OFIRMEV. If our sales of OFIRMEV are insufficient to meet our minimum annual royalty obligations, we will be required to make larger royalty payments than would have otherwise been required based on sales of OFIRMEV alone. 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 a limited history of revenue and may never be profitable.***

Our ability to become profitable depends upon our ability to generate revenue. We began to market OFIRMEV in January 2011, and we had not generated any revenue prior to that time. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- effectively commercialize OFIRMEV;
- manufacture commercial quantities of OFIRMEV at acceptable cost levels;
- successfully manage our commercial organization and the supporting infrastructure required to successfully market and sell OFIRMEV; and
- obtain regulatory approval for any other product candidates that we may license or acquire.

We have incurred and anticipate continuing to incur significant costs associated with our efforts to commercialize, market and sell OFIRMEV. 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. Prior to 2011, our operations were limited to organizing and staffing our company, in-licensing and conducting product development activities, including clinical trials and manufacturing development activities, and preparing to commercialize OFIRMEV. In January 2011, we launched OFIRMEV and began generating revenues. OFIRMEV is still in the early stages of commercialization, and we have not yet demonstrated an ability to successfully market and sell OFIRMEV or any other 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 commercializing pharmaceutical products.

### ***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:

- our ability to successfully market and sell OFIRMEV;
- our capacity to manage our commercial infrastructure and related expenses, including our recently hired sales and marketing personnel and our agreements 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 development programs for any future product candidates;
- costs associated with our ongoing intellectual property infringement lawsuits related to OFIRMEV, and any product liability or other litigation in which we may become involved;

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- costs associated with any product recall or investigation into quality concerns;
- regulatory developments affecting OFIRMEV or the product candidates of our competitors;
- the level of underlying hospital demand for OFIRMEV and wholesalers' buying patterns; and
- any determination to exercise our option to acquire Incline.

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. For example, we undertook a public offering of our common stock in November 2010 through which we issued a total of 12.5 million shares and raised net proceeds of \$93.6 million, and in November 2011 we issued a total of 21.8 million shares of common stock in a public offering and raised net proceeds of \$77.3 million. If we raise additional funds through alternative means such as 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 December 2011, we refinanced our \$30.0 million secured credit facility with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation. This secured credit facility 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 current 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 current 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 and potential foreclosure on the assets pledged to secure the 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

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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.

In addition, in July 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access, and the SEC has since issued final rules implementing “say on pay” measures. Our efforts to comply with corporate governance and related requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management’s time from other business activities.

### ***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, 2011, we have generated federal and state net operating loss carryforwards of approximately \$306.5 million and \$310.0 million, respectively. We also have federal and state research and development tax credit carryforwards of approximately \$4.8 million and \$2.8 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. Our federal tax credits will begin expiring in 2024 unless previously used and our state tax credits carryforward indefinitely. Additionally, under Internal Revenue Code Sections 382 and 383, the annual use of our net operating loss carryforwards and research tax credits will be limited in the event a cumulative change in our ownership occurs within a three-year period. We expect to complete an analysis as to whether such a change of ownership has occurred in the next 12 months, and in such an event, we 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 difficult 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, fluctuating business and consumer confidence and continued unemployment concerns, have precipitated significant economic uncertainty. 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 continuing market turbulence, 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 decline.

## Risks Relating to Securities Markets and Investment in Our Stock

*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 recently experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Continued volatility in the overall capital markets 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, 2011 ranged from a high of \$10.00 to a low of \$3.41. 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 our operating results and the hospital formulary acceptance of OFIRMEV;
- 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 to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments pertaining to the ANDAs relating to OFIRMEV, including any future ANDA filings, and any other challenges to our patents and other intellectual property rights;
- developments concerning product development results or intellectual property rights of others;
- product recalls, quality concerns or manufacturing difficulties;
- 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

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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, we undertook public offerings of our common stock through which we issued totals of 21.8 million shares of common stock in November 2011 and 12.5 million shares of common stock in November 2010, and in May 2009, we completed the registration of approximately 18.1 million 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. 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.

Furthermore, any future equity financing we may undertake, or the expectation of such financing, could reduce the market price of our common stock over dilution concerns. 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, 2011, our executive officers and directors and their affiliates together controlled approximately 30.0% 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 president or by a majority of the total number of directors;
- advance notice requirements for stockholder proposals and nominations;
- a requirement of approval of not less than 66-2/3% 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.

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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 current loan and security agreement with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation 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 currently lease approximately 23,500 square feet of space in our headquarters in San Diego, California under a lease that expires in December 2013. In September 2012, we will relinquish approximately 6,900 square feet under the terms of the agreement and occupy the remaining 16,600 square feet through the term of the lease. We have no laboratory, research, manufacturing or warehouse facilities; however we do own manufacturing equipment located at a third-party contractor. 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***

In August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock Laboratories, Inc., Perrigo Company and Paddock Laboratories, LLC, collectively referred to herein as Paddock, and against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc.,



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collectively referred to herein as Exela. The lawsuit follows the notices that we received in July 2011 from each of Paddock and Exela concerning their filings of Abbreviated New Drug Applications, or ANDAs, containing a “Paragraph IV” patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit, we allege that Paddock and Exela have each infringed U.S. Patent Nos. 6,028,222, or the ‘222 patent, and 6,992,218, or the ‘218 patent, by filing their respective ANDAs seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The ‘222 and the ‘218 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA until the earlier of the expiration of a 30-month period, the expiration of the ‘222 and ‘218 patents, the entry of a settlement order or consent decree stating that the ‘222 and ‘218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Paddock or Exela, or such shorter or longer period as the Court may order. Each of Paddock and Exela has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed counterclaims. A date for the bench trial in this case has been tentatively scheduled for May 2013.

Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. Specifically, the FDA has granted OFIRMEV three years of regulatory exclusivity, which expires November 2, 2013. We intend to vigorously enforce our intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of our patents. The ‘222 patent expires August 5, 2017 (or February 5, 2018 if pediatric exclusivity is granted) and the ‘218 patent expires June 6, 2021 (or December 21, 2021 if pediatric exclusivity is granted). However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or any other litigation. Regardless of how this litigation is ultimately resolved, this matter may be costly, time-consuming and distracting to our management, which could have a material adverse effect on our business.

#### **Item 4. *Mine Safety Disclosures***

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 is traded on the NASDAQ Global Market under the symbol "CADX." As of February 29, 2012, there were 85,516,607 shares of common stock outstanding held by approximately 20 stockholders of record. Many stockholders hold their shares in street name and we believe that there are more than 4,000 beneficial owners of our common stock. The closing price of our common stock on the NASDAQ Global Market on December 30, 2011, the last trading day in 2011, was \$3.95 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:

Period:	Year Ended December 31,			
	2011		2010	
	High	Low	High	Low
First Quarter	\$ 9.21	\$7.05	\$10.91	\$8.41
Second Quarter	\$10.00	\$6.94	\$10.63	\$6.29
Third Quarter	\$ 9.47	\$5.80	\$ 8.60	\$6.59
Fourth Quarter	\$ 6.99	\$3.41	\$10.00	\$7.13

**Securities Authorized for Issuance under Equity Compensation Plans**

The following table provides information as of December 31, 2011, about our common stock that may be issued upon the exercise of stock options and the vesting of restricted stock units granted to employees 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. We amended and restated this plan in April 2010, which became effective in May 2010 upon the approval by our stockholders. See Note 11 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**

Plan Category:	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)
Equity compensation plans approved by security holders	7,973,609 <sup>(1)</sup>	\$ 8.21 <sup>(2)</sup>	1,014,264 <sup>(3)</sup>
Equity compensation plans not approved by security holders.	—	—	—
Total	<u>7,973,609</u>	<u>\$ 8.21<sup>(2)</sup></u>	<u>1,014,264<sup>(3)</sup></u>

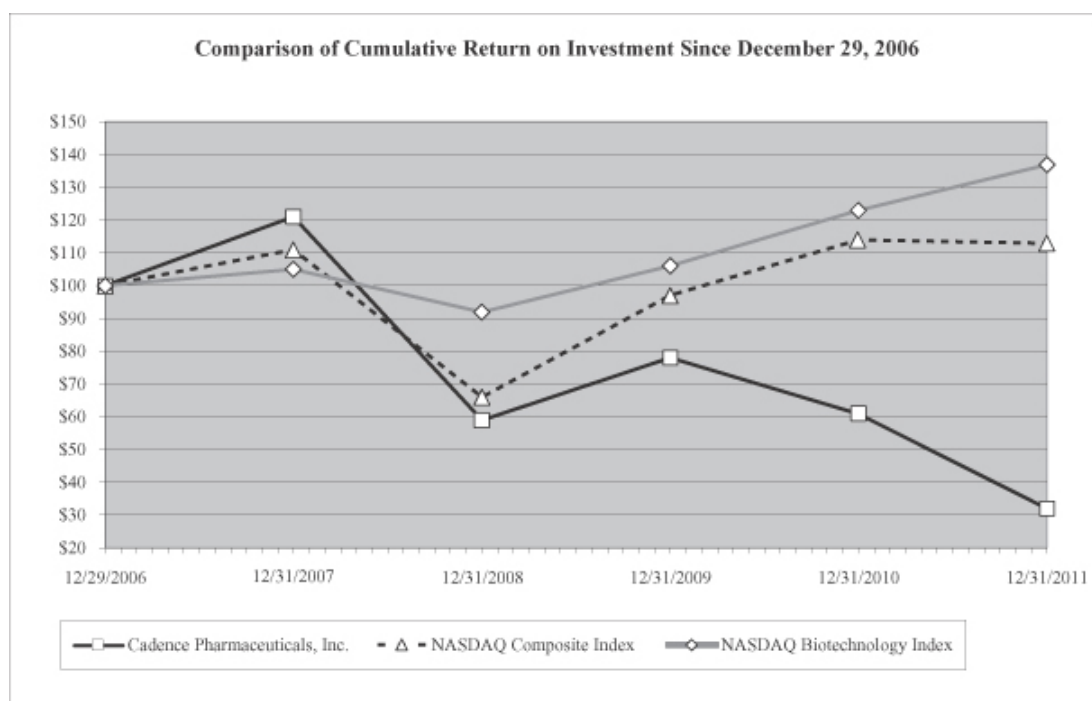
<sup>(1)</sup> Of these shares of common stock, 6,937,755 shares were subject to outstanding options under the 2006 Equity Incentive Award Plan and 1,031,478 shares were subject to outstanding options under the 2004 Equity Incentive Award Plan. In addition, 4,376 of the shares were subject to outstanding restricted stock units under the 2006 Equity Incentive Award Plan.

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- (2) As restricted stock units do not have an exercise price, the weighted average exercise price does not take into account the 4,376 restricted stock units outstanding 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 through January 1, 2016. The annual increase in the number of shares shall be equal to the lesser of (1) 4% of our outstanding common stock on the applicable January 1 or (2) such lesser amount determined by our board of directors. At January 1, 2011, 2010, 2009 and 2008, the board of directors approved the amount of shares authorized for future issuance under the 2006 Plan to be increased by 1,893,220 shares, 1,766,960 shares, 1,269,576 shares and 1,018,939 shares, respectively, under this provision. Effective January 1, 2012, the board of directors authorized an additional 3,334,952 shares for future issuance under the 2006 Plan pursuant to the provision; however, the issuance of such shares under the 2006 Plan is subject to shareholder approval of an amendment to our amended and restated certificate of incorporation to increase our authorized shares of common stock.

## Performance Graph

The following stock performance graph illustrates a comparison of the total cumulative stockholder return on our common stock to two indices; the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of \$100 at the close of business on December 29, 2006, the last trading day in 2006, and that all dividends, if any, were reinvested. 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

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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 Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation. 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, 2011 and 2010 and the related audited statements of operations and of cash flows for each of the three years in the period ended December 31, 2011 and notes thereto appear elsewhere in this Annual Report on Form 10-K. Audited balance sheets at December 31, 2009, 2008 and 2007 and the related audited statements of operations and of cash flows for 2008 and 2007 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.

(in thousands, except per share data)	Year Ended December 31,				
	2011	2010	2009	2008	2007
<b>Statement of Operations Data:</b>					
Product revenue, net	\$ 11,486	\$ —	\$ —	\$ —	\$ —
License revenue	5,210	—	—	—	—
Total net revenue	16,696	—	—	—	—
Cost of product sales	12,406	—	—	—	—
Amortization of patent license	1,567	—	—	—	—
Research and development	8,885	13,757	19,464	40,018	41,781
Selling, general and administrative	81,504	39,347	24,620	14,131	12,453
Other	1,076	1,813	413	2,384	—
Loss from operations	(88,742)	(54,917)	(44,497)	(56,533)	(54,234)
Interest income	136	106	182	1,530	3,404
Interest expense	(4,424)	(2,144)	(1,137)	(1,916)	(867)
Other income (expense)	9	312	(39)	(180)	(17)
Net loss	<u>\$(93,021)</u>	<u>\$(56,643)</u>	<u>\$(45,491)</u>	<u>\$(57,099)</u>	<u>\$(51,714)</u>
Basic and diluted net loss per share <sup>(1)</sup>	<u>\$ (1.41)</u>	<u>\$ (1.09)</u>	<u>\$ (0.93)</u>	<u>\$ (1.55)</u>	<u>\$ (1.81)</u>

<sup>(1)</sup> There is a lack of comparability in the per share amounts between the periods presented as a result of the issuance of 21,800 shares of common stock pursuant to a public offering in the fourth quarter of 2011, 12,500 shares of common stock pursuant to a public offering in the fourth quarter of 2010, 12,040 shares of common stock pursuant to a private placement in the first quarter of 2009 and 9,240 shares of common stock pursuant to a registered direct offering in the first quarter of 2008 .

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(in thousands)	As of December 31,				
	2011	2010	2009	2008	2007
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities	\$ 127,227	\$ 134,141	\$ 82,006	\$ 47,627	\$ 55,393
Accounts receivable, net	2,703	—	—	—	—
Inventory	1,388	485	—	—	—
Working capital	116,892	121,319	67,193	28,385	36,839
Total assets	164,160	163,786	92,563	55,148	64,612
Long-term debt, less current portion and discount	28,696	24,654	—	6,098	13,412
Accumulated deficit	(366,683)	(273,662)	(217,019)	(171,528)	(114,429)
Total stockholders' equity	119,310	123,960	75,063	26,440	28,458

**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. For a complete discussion of forward-looking statements, see the section above entitled "Forward-Looking Statements." 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 the section above entitled "Risk Factors."*

**Overview**

We are a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. 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 unmet commercial potential. We will also consider strategically attractive opportunities to co-promote commercialized hospital products.

In 2006, we in-licensed the exclusive U.S. and Canadian rights to OFIRMEV<sup>®</sup> (acetaminophen) injection, an intravenous formulation of acetaminophen, from BMS, which currently markets the product in Europe and several other markets under the brand name Perfalgan<sup>®</sup>. In November 2010, OFIRMEV was approved by the FDA, and we commercially launched OFIRMEV in the U.S. in January 2011. Our near-term business strategy since the launch of OFIRMEV has been, and continues to be, working with physicians and hospitals to increase demand for OFIRMEV and ensure formulary adoption. We believe this strategy will position us well for continued revenue growth. For example, during the year ended December 31, 2011, our initial launch year, we recognized \$11.5 million of net revenue on sales of OFIRMEV, and the product was added to the formulary lists at approximately 1,580 hospitals.

As part of our long-term business strategy, we entered into an agreement with Incline in June 2010 that provides us with the exclusive, irrevocable option to acquire Incline within a specified future time period. Incline is developing IONSYS<sup>™</sup> (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery. We believe that, if approved by the FDA, IONSYS could represent a potentially significant commercial opportunity and be an excellent strategic fit with OFIRMEV. As consideration for the option, we paid Incline a \$3.5 million upfront option fee in June 2010 and made a second payment of \$3.5 million in September 2011 upon Incline's receipt of the second tranche of its Series A financing. We are currently in the second of two option periods, which extends until the earliest to occur of (1) 30 days after the date on which Incline submits a supplemental NDA for IONSYS to the FDA, (2) 30 days after the filing of an initial public offering by Incline, or (3) 42 months after the effective date of the option (December 21, 2013). During this second option period, we may acquire Incline for an amount not to exceed \$228.0 million plus payment of an additional amount not to exceed \$57.0 million upon FDA approval of IONSYS. We have an exclusive right of first negotiation to acquire Incline for the six-month period following the expiration of the second option period. In addition, we may elect to extend the second option period for two additional three-month periods upon the payment of \$2.5 million to Incline for each period. Incline will remain primarily responsible for the development of IONSYS. However, we and Incline have formed a joint development committee to oversee the global development and regulatory approval for the IONSYS product candidate.

In executing our business strategy, we have incurred significant net losses since our inception and have financed our operations primarily through the sale of equity securities in both public and private offerings. Most recently, we sold 21.8 million shares in a public offering in the fourth quarter of 2011 and received aggregate net proceeds of approximately \$77.3 million (after underwriting discounts and offering costs). From inception through December 31, 2011, we have received net proceeds of approximately \$443.7 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Additionally, we have entered into

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multiple loan and security agreements with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation to provide us with growth capital. As of December 31, 2011, the principal balance outstanding on our current facility with this loan syndicate was \$30.0 million.

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 on our website at [www.cadencepharm.com](http://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. We own or have rights to various trademarks, copyrights and tradenames used in our business, including the following: Cadence®, OFIRMEV® and the OFIRMEV logo.

This report also contains trademarks of other companies, including IONSYSTM, a registered trademark of Incline, Perfalgan®, a registered trademark of BMS, and Caldolor® a registered trademark of Cumberland Pharmaceuticals, Inc.

### ***OFIRMEV Revenue***

In January 2011, we commercially launched OFIRMEV and began shipping product to independent wholesalers who sell OFIRMEV to hospitals and other end-user customers. Our initial focus was to promote rapid hospital formulary adoption of the product. During the year ended December 31, 2011, we succeeded in obtaining formulary approval for OFIRMEV at approximately 1,580 hospitals, including major academic medical centers and large community healthcare systems. During the second half of 2011, our sales force placed additional focus on generating pull-through hospital sales of OFIRMEV with the result that, in the fourth quarter of 2011, we reported net revenue from sale of OFIRMEV of \$5.9 million, an amount that exceeded the \$5.6 million of net revenue reported for the first three quarters of 2011 combined. For the year ended December 31, 2011, we realized \$11.5 million of net revenue on shipments of OFIRMEV to over 2,200 hospitals and other end-user customers. A total of approximately 1.2 million vials of OFIRMEV were sold during 2011.

### ***License Revenue***

In November 2010, we entered into a data license agreement with Terumo Corporation, or Terumo, and Pharmatop. As part of the data license agreement, we provided to Terumo certain data and information resulting from our clinical development program for OFIRMEV for Terumo's use in obtaining regulatory approval for and commercializing the same intravenous formulation of acetaminophen in Japan. Further, we are to provide to Terumo, without charge, up to 500 hours of technical assistance and consulting services in relation to the licensed technical information, data and know-how in order to assist Terumo in obtaining regulatory approval and manufacturing capacity for the product candidate. In April 2011, we received an upfront payment of \$5.3 million under the terms of the data license agreement. If Terumo is successful in its efforts to obtain regulatory approval for and commercialize the product in Japan, we may be entitled to an additional lump-sum payment upon the first commercial sale of the product candidate and royalty payments upon any commercial sales of the product in Japan.

During the year ended December 31, 2011, we recognized \$5.2 million of licensing revenue under the data license agreement with Terumo for the data provided and consulting hours incurred. The remaining payment balance of \$0.1 million reflects the value of the outstanding consulting hours we are obligated to provide under the terms of the contract through November 2012. This balance is recorded as deferred revenue on our balance sheet at December 31, 2011 and will be recognized as revenue as the consulting services are rendered. No similar revenue was recognized during the year ended December 31, 2010.

### ***Cost of Sales***

Our cost of sales consists primarily of our third-party manufacturing costs, internal manufacturing overhead, indirect and personnel overhead costs, freight, excess or obsolete inventory adjustment charges and the cost of purchasing the active pharmaceutical ingredient for OFIRMEV, acetaminophen. Further, cost of sales includes the royalties due under our license agreement with BMS, which range from the mid-teens to the mid-twenties, depending on the aggregate amount of net sales we record per contract year. During the year ended 2011, we reported total costs of sales of \$12.4 million, which included additional start-up manufacturing expenses and unabsorbed costs resulting from periods of idle manufacturing capacity at our primary third-party manufacturing facility. Additionally, for 2011 our costs of sales included a charge for inventory losses of \$5.6 million to write-down certain inventory to its estimated net realizable value. The product in question was placed on indefinite hold pending the outcome of an investigation into unidentified particulate matter observed during routine product stability testing. The charge is being recorded due to uncertainty as to the amount of time that may be required to complete the investigation and whether the product will have sufficient remaining shelf life or otherwise be saleable after the investigation is completed.

### ***License Fees and Patent Amortization***

As a result of the FDA's approval of OFIRMEV, we paid a \$15.0 million license fee in the fourth quarter of 2010 pursuant to the term of our license agreement with BMS. This payment was capitalized on our balance sheets as an intangible asset and we are amortizing the balance on a straight-line basis, based upon the estimated life of the underlying patent assets. We may be required to make two additional milestone payments totaling up to \$25.0 million based upon the achievement of certain levels of net sales of OFIRMEV, which will be recognized as license fees in the period they are incurred, as appropriate. In addition, we paid a \$25.0 million up-front license in 2006 to acquire the rights to OFIRMEV, which was immediately expensed as the asset had no established technological feasibility or alternative future use at that time.

### ***Research and Development Expenses***

Our historical research and development expenses relate predominantly to OFIRMEV and our discontinued omiganan pentahydrochloride product candidate. These expenses have consisted of salaries and related employee benefits for our research and development team, license fees paid to our licensors prior to approval of our drug candidates, pre-commercialization manufacturing development activities, costs associated with clinical trials, and costs associated with non-clinical activities, such as expenses related to regulatory submissions. We have expensed these charges as the costs were incurred in developing, testing and seeking marketing approval of our product candidates. We received marketing approval for OFIRMEV from the FDA in November 2010 and with our OFIRMEV program continuing to progress, we implemented a restructuring of our workforce in November 2011 to focus our resources on the commercialization of OFIRMEV and reduce program costs that are not directly related to such efforts. This action resulted in a reduction in force of 12 employees in research and development.

We expect to continue to incur research and development expenses related to OFIRMEV, however, it is difficult to anticipate the scope and magnitude of our future research and development expenses. For example, the FDA has required that we complete a post-approval clinical trial for OFIRMEV in pediatric patients under two years of age, and we may also conduct clinical studies to expand the indications for OFIRMEV. 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.

### ***Selling, General and Administrative Expenses***

Our selling, general and administrative expenses consist primarily of salaries and related employee benefits for our sales and marketing staff; advertising, marketing and other promotional costs for OFIRMEV; selling



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expenses for our sales representatives, including travel-related costs; salaries and related employee benefits for our administrative, finance, human resources, legal, business development and internal systems support functions; costs incurred in relation to our medical affairs programs, including salaries, related employee benefits and costs incurred by our medical science liaisons; as well as the related professional fees for these functions, insurance and facility costs.

Our selling, general and administrative costs have increased significantly since we began to focus significant resources on establishing our commercial organization in preparation for the commercial launch of OFIRMEV. Following approval of OFIRMEV in November 2010, we hired and trained our sales force and related personnel, including dedicated, hospital-focused sales representatives covering territories across the U.S. These sales representatives are focusing their efforts on the top 1,800 to 1,900 U.S. hospitals, which we believe represent approximately 80% of the market opportunity for OFIRMEV. We expect to continue to incur significant selling, general and administrative expenses as we continue to execute our marketing and sales strategies for OFIRMEV and implement a variety of marketing programs to educate customers about OFIRMEV.

### ***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 incur under our loan and security agreements and the amortization of debt issuance costs. Other income and expense includes federal grants we have received, gains or losses recognized on transactions denominated in foreign currencies and other transactions not related to our operations.

### ***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, 2011, we had federal and state net operating loss carryforwards of approximately \$306.5 million and \$310.0 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 \$4.8 million and \$2.8 million, respectively. The federal tax credits will begin expiring in 2024 unless previously utilized and the state tax credits carryforward indefinitely. Under Sections 382 and 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 but expect to complete the analysis within the next 12 months and, as a result, we may have a change in the unrecognized tax benefits that are recorded. 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 and, due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

### ***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

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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 the recognition of revenue; the valuation of our inventory, which impacts gross margin; 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 review our estimates, judgments, and assumptions used in our accounting practices 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, our actual results may differ from these estimates.

### ***Revenue Recognition***

We sell OFIRMEV to wholesalers and directly to hospitals. Our distribution channel includes our sales representatives, our third party logistics distributor and independent wholesalers who distribute the product directly to hospitals and other end-user customers. The majority of our shipments are made to wholesalers, with whom we have contracted to distribute the product. We have also contracted with group purchasing organizations to increase awareness of, and reduce market barriers for, OFIRMEV.

Our wholesaler agreements provide selling prices that are fixed on the date of sale, although we offer certain discounts to group purchasing organizations and governmental programs. The wholesalers take title to the product, bear the risk of loss of ownership and have economic substance to the inventory. Further, we have no significant obligations for future performance to generate pull-through sales, however we do allow our wholesalers to return product that is damaged or received in error. Additionally, we allow for product to be returned beginning six months prior to, and ending twelve months following, product expiration. As OFIRMEV is our first and only commercially available product and we have a limited amount of product return data, we do not believe we currently have sufficient history to accurately predict product returns from our wholesaler distribution channel. Therefore, we are deferring the recognition of revenue until the wholesalers sell OFIRMEV to hospitals or other end-user customers. We will continue to defer recognition until the point at which we have obtained sufficient sales history to accurately estimate returns from the wholesalers, which to date have been minimal. Shipments of product that are not recognized as revenue are treated as deferred revenue until evidence exists to confirm that pull-through sales to hospitals or other end-user customers have occurred.

We record certain fees, sales reserves and allowances as a reduction to gross revenue and deferred revenue, as applicable. These reserves and allowances include distribution service fees, a prompt payment reserve, a group purchasing discount and administrative service fee, and discounts to governmental programs, as applicable. Distribution service fees arise from contractual agreements between us and certain wholesalers for distribution services they provide with respect to OFIRMEV. These fees are generally a fixed percentage of the price of the product purchased by these wholesalers. The prompt payment reserve is based upon cash discounts we offer certain wholesalers as an incentive to meet certain payment terms. We account for these cash discounts at the time the sale is made to the wholesalers and reduce our accounts receivable accordingly. The group purchasing discount and administrative service fee is based upon contracted discounts we provide to members of certain purchasing groups. We estimate the sales through our wholesalers to the group purchasing organization members and accrue for the chargebacks we anticipate from such sales based on the difference between the current retail price and the reduced price paid by the group purchasing organization members. A group purchasing

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organization administrative fee that we incur in exchange for administrative services provided by the group purchasing organizations for these transactions is also recorded at the time of sale. We also provide governmental programs a predetermined discount that is recorded at the time of sale.

Revenue from our data license agreement is recognized upon delivery of the goods and services provided, based upon the consideration allocated to each deliverable. We allocated the consideration to each deliverable based upon our review of the agreement pursuant to multiple-element arrangement guidance. We determined both the data license and consulting service deliverables were separate units of accounting, each having value on a standalone basis, and estimated the fair value each item. The value of the data license was based upon similar proposals from third parties and internal costs we incurred in developing the data and obtaining similar rights. The value of the consulting services was based on contracts we had engaged with third parties for similar services. These values were consolidated and adjusted based upon the relative fair value of the consideration received pursuant to the agreement and there is no right of return or similar refund provisions in the data license agreement. Consideration allocated to the data license was recognized as revenue upon delivery of the data in 2011. Consideration allocated to the consulting services is being recognized as revenue as such services are rendered.

### ***Inventories***

We state our inventories at the lower of cost or market. We use a combination of standard and actual costing methodologies to determine the cost basis for our inventories. These methodologies approximate actual costs on a first-in, first-out basis. In addition to stating inventory at the lower of cost or market, we also evaluate our inventories each period for excess quantities and obsolescence. This evaluation includes identifying those items specifically identified as obsolete and analyzing forecasted demand versus quantities on hand so that this inventory can be valued appropriately.

Our inventory costs consist primarily of our third-party manufacturing fees, internal manufacturing overhead, indirect and personnel overhead costs, freight-in and the cost of purchasing acetaminophen, the active pharmaceutical ingredient for OFIRMEV. Fixed production overheads are allocated to the unit production costs based upon normal production capacity. Unallocated overhead costs incurred during periods of abnormally low production or unplanned facility downtime are recognized as expense in the period in which they are incurred.

For 2011, we recorded a charge for inventory losses of \$5.6 million in cost of sales to write-down certain inventory to its estimated net realizable value. The product in question was placed on indefinite hold pending the outcome of an investigation into unidentified particulate matter observed during routine product stability testing. The charge is based upon our best estimate of the value we will realize from the sale, if any, of the product and is being recorded due to uncertainty as to the amount of time that may be required to complete the investigation and whether the product will have sufficient remaining shelf life or otherwise be saleable after the investigation is completed.

### ***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 date 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.

### ***Long-Lived Assets***

A substantial portion of our capital assets are associated with our manufacturing equipment at Baxter, our primary third-party manufacturer. In building these assets and creating additional capacity, we have entered into

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agreements whereby we fund specified improvements to the facilities and the construction of the manufacturing equipment to be used for the production of OFIRMEV. During the build-out of the facility and construction of our equipment, we accrue for costs incurred based on factors such as estimates of work performed, milestones achieved and experience with similar contracts. As actual costs become known, we adjust our accruals accordingly.

We evaluate these 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 it by \$0.2 million as actual costs incurred in disposing of the assets were less than anticipated. Additionally, during the second quarter of 2010, we modified the design of our planned second production line for our OFIRMEV product candidate resulting in the partial cancellation of a capital equipment order. As a result of the partial cancellation of the equipment, we incurred a charge of \$1.5 million in 2010 to impair the costs accumulated in construction-in-process for the equipment and accrue for related termination charges.

## **Results of Operations**

### ***Years ended December 31, 2011 and 2010***

#### ***Revenue***

During the year ended December 31, 2011, our initial launch year for OFIRMEV, we recognized \$11.5 million of net product revenue from the sale of OFIRMEV to hospitals and other end-users. Additionally, we recognized \$5.2 million of revenue during 2011 related to the data license agreement with Terumo, for which data was provided and consulting hours were incurred pursuant to the terms of the agreement. No similar revenue was recognized during the year ended December 31, 2010.

Our product revenue is reported net of fees, sales reserves and allowances, including the distribution service fee we pay to our contracted wholesalers, a prompt payment reserve we grant our customers, a group purchasing discount and administrative service fee, and discounts to governmental programs, as applicable. Further, although title to the product and risk of loss pass to the wholesalers upon delivery to them, we are deferring the recognition of revenue to the point at which the product is sold to hospitals and other end-user customers due to our lack of sufficient sales returns history to accurately estimate returns from the wholesalers. Revenue from product sales that remains with the wholesalers at period-end is recorded as deferred revenue, which as of December 31, 2011, was \$1.2 million, net of fees, sales reserves and allowances. We had no deferred revenue at December 31, 2010.

#### ***Costs and Expenses***

*Cost of Product Sales.* Our cost of product sales for the year ended December 31, 2011, was \$12.4 million and includes a charge recorded in the fourth quarter of 2011 of \$5.6 million. Further, our cost of sales for 2011

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includes higher per-unit costs as we commenced the manufacturing of OFIRMEV, resulting in inefficiencies and higher allocated overhead costs. Additionally, we incurred certain periods of idle manufacturing capacity, resulting in unabsorbed manufacturing costs, mostly attributable to depreciation expense and labor-related costs. These costs were recognized as a cost of product sales during the period in which they were incurred.

*Patent Amortization.* For the year ended December 31, 2011, we incurred \$1.6 million of non-cash expense related to the amortization of the \$15.0 million license payment made to BMS following the approval of our NDA for OFIRMEV in November 2010. We are amortizing the balance of the payment on a straight-line basis, based upon the estimated life of the underlying patent assets. No such amortization was incurred during the year ended December 31, 2010.

*Research and Development Expenses.* Research and development expenses decreased \$4.9 million for the year ended December 31, 2011, to \$8.9 million, compared to \$13.8 million for 2010. This decrease was due to the completion of our development program for OFIRMEV, and transition to a commercially-focused organization. Specifically, in 2010, we incurred manufacturing development expenses in preparation for the commercialization of OFIRMEV that were not incurred in 2011. Further, during 2011, certain quality assurance expenses incurred in the manufacturing process for OFIRMEV were allocated to manufacturing, which we did not incur in 2010. In November 2011, we continued this transition by implementing a restructuring of our workforce, resulting in the reduction of 12 employees in our research and development organization.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased by \$42.2 million for the year ended December 31, 2011, to \$81.5 million, compared to \$39.3 million for 2010. This increase was primarily related to costs associated with our sales representatives, who were hired following the FDA approval of OFIRMEV in November 2010. These additional costs include the labor-related costs for the sales representatives and the related support staff. Other added costs include the travel expenses incurred by our sales representatives and other selling and education related costs. Further, we incurred additional marketing and promotion expenses, medical affairs costs, legal fees and other general corporate expenses in support of our commercial operations during 2011, as compared to 2010.

*Other Expenses.* In November 2011, we implemented a restructuring of our workforce, which resulted in the termination of 17 employees, or approximately 7% of our total workforce at that time. The reduction was primarily in our research and development and general and administrative areas. As a result, we recorded one-time employee termination costs of \$1.1 million, including severance and other benefits. These costs were partially offset by a \$0.3 million recovery of previously accrued labor related charges, which was recorded at the time of the termination and is included in research and development expenses. In 2010, we recorded a charge of \$1.5 million related to the partial cancellation of an equipment order resulting from a modification in the design of our planned second production line for OFIRMEV. The charge recorded impaired the costs that had been accumulated in construction-in-progress for the equipment. Further, we incurred a charge of \$0.3 million related to a reduction in force of six individuals during the second quarter of 2010.

### ***Other Income and Expenses, Net***

Net other expense increased \$2.6 million for the year ended December 31, 2011, to \$4.3 million, compared to \$1.7 million in 2010. This increase was primarily due to the additional interest expense incurred under our loan and security agreement and the amendments thereto, and a higher outstanding principal balance during the year ended December 31, 2011, as compared to the same period in 2010. Further, in 2010, we received a \$0.2 million federal government grant from the Qualifying Therapeutic Discovery Project program under section 48D of the Internal Revenue Code. No similar grants were received in 2011.

**Years ended December 31, 2010 and 2009**

**Costs and Expenses**

*Research and Development Expenses.* Research and development expenses decreased \$5.7 million for the year ended December 31, 2010, to \$13.8 million, compared to \$19.5 million for 2009. This decrease was due to the progress of our development programs during this period. More specifically, in May 2009, we completed the clinical trial program for OFIRMEV and filed an NDA for the product with the FDA. As a result, our research and development spending on this program decreased \$3.6 million in 2010 as compared to 2009. Further, as we discontinued our omiganan pentahydrochloride product candidate in March 2009, our spending for this program decreased \$1.7 million in 2010 as compared to 2009. In addition, our other supporting costs related to these programs also decreased \$0.4 million in 2010 as compared to 2009.

*Selling, General and Administrative Expenses.* For the year ended December 31, 2010, our selling, general and administrative expenses increased \$14.7 million to \$39.3 million, compared to \$24.6 million for 2009. This increase was primarily related to our efforts to establish our commercial infrastructure and prepare for the commercial launch of OFIRMEV. As part of these efforts, we increased our sales and marketing staff from two at the beginning of 2009 to approximately 200 at December 31, 2010. This increase in personnel significantly increased our salaries and related personnel costs in 2010 as compared to 2009, including an additional \$2.3 million of stock-based compensation charges. Moreover, we incurred additional consulting and other services related to the establishment and operating costs of our commercial infrastructure in 2010.

*Other Expenses.* For the year ended December 31, 2010, we recorded a charge of \$1.5 million related to the partial cancellation of an equipment order resulting from a modification in the design of our planned second production line for OFIRMEV. The charge recorded impaired the costs that had been accumulated in construction-in-progress for the equipment. Further, we incurred a charge of \$0.3 million related to a reduction in force of six individuals during the second quarter of 2010. During 2009, we recorded restructuring charges of \$0.6 million related to the discontinuation of our omiganan pentahydrochloride product candidate. Additionally in 2009, we reduced the impairment charge taken in the fourth quarter of 2008 on our omiganan pentahydrochloride manufacturing equipment by \$0.2 million as the actual costs incurred in disposing of certain assets were less than anticipated.

**Other Income and Expenses, Net**

Net other expense increased \$0.7 million for the year ended December 31, 2010, to \$1.7 million, compared to \$1.0 million in 2009. This increase was primarily due to the additional interest expense incurred on the additional outstanding principal balance under our loan and security agreement. Partially offsetting the increase in interest expense was the receipt of \$0.2 million in federal government grants from the Qualifying Therapeutic Discovery Project program under section 48D of the Internal Revenue Code in 2010. No similar grants were received in 2009.

**Liquidity and Capital Resources**

As a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting, we enter into agreements to acquire the rights to develop and commercialize product candidates. These agreements and related development programs consume significant resources and may not result in a commercial product to generate revenue. For example, we obtained the exclusive patent rights and know-how for OFIRMEV, which is currently our only product, for the U.S. and Canada pursuant to our license agreement with BMS. Under this agreement, we have paid a total of \$40.0 million in up-front fees and milestone payments, and we may be required to make two future milestone payments totaling up to \$25.0 million upon the achievement of certain levels of net sales of the product. We are also obligated to pay royalties on any net sales of OFIRMEV, and are subject to annual minimum royalty obligations. Further, in the second quarter of 2010 we entered into an option agreement pursuant to which we

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obtained an option to acquire Incline. As consideration for this option, we have paid a total of \$7.0 million to Incline. Our agreement with Incline is currently in the second of two option periods, during which we may acquire Incline for an amount not to exceed \$228.0 million, plus payment of an additional amount not to exceed \$57.0 million upon FDA approval of IONSYS.

In developing these products, we incur substantial capital resource outlays which we may not recover quickly, or at all. For example, we have incurred over \$43.0 million in research and development costs through December 31, 2011 specific to the OFIRMEV development program. Our total investment in the OFIRMEV program is significantly more as these costs exclude a substantial portion of our internal costs, such as salaries and related personnel costs, which are not tracked on a project basis. In January 2011, we commenced sales of OFIRMEV, however, as of December 31, 2011, we have realized less than \$12.0 million in net revenue and we continue to operate at a loss. We 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. We incurred expenses of approximately \$57.5 million specific to the omiganan project, which was discontinued in 2009.

We have incurred significant net losses since our inception and, as of December 31, 2011, we had accumulated a deficit of \$366.7 million. A significant portion of these costs have been incurred in connection with research and development activities, including license fees, costs of clinical trial activities associated with our product candidates, our commercial operations and infrastructure, manufacturing development activities and general and administrative expenses. We have continued to incur operating losses in connection with our commercial launch of OFIRMEV, including the marketing and sales efforts for the product, and expect to continue operating at a loss until we can generate a sufficient amount of revenue from sales of OFIRMEV. Further, we could incur additional expenses, which may be significant, if we acquire or in-license additional products, technologies or businesses that are complementary to our own.

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

- our ability to successfully market and sell OFIRMEV;
- our capacity to manage our commercial infrastructure and related expenses, including our sales and marketing personnel, and costs incurred under our agreements with third parties for warehousing, distribution, cash collection and related commercial activities;
- our execution of acquisition, in-licensing, co-promotion, or similar agreements for new products, and the timing of payments we may make or receive under these agreements;
- variations in the level of expenses related to our development programs for any future product candidates;
- costs associated with our ongoing intellectual property infringement lawsuits related to OFIRMEV, and any product liability or other litigation in which we may become involved;
- costs associated with any product recall or investigation into quality concerns;
- regulatory developments affecting OFIRMEV or the product candidates of our competitors;
- the level of underlying hospital demand for OFIRMEV and wholesalers' buying patterns; and
- any determination to exercise our option to acquire Incline.

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Since inception, our operations have been financed primarily through the sale of equity securities, in both public and private offerings. From our inception through December 31, 2011, we have received net proceeds of approximately \$443.7 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Through December 31, 2011, the sales of shares of our preferred stock, common stock and warrants were as follows:

- from July 2004 to December 2011 (excluding our initial public offering, our February 2008 registered direct offering, our February 2009 private placement and our 2010 and 2011 public offerings), we issued and sold a total of 3,060,822 shares of common stock to our founders, employees, directors and consultants for aggregate net proceeds of \$2.7 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;
- 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 at a price of \$7.84, all of which remain outstanding at December 31, 2011;
- in November and December 2010, we completed a public offering in which we issued and sold a total of 12,500,000 shares of our common stock for aggregate net proceeds of \$93.6 million; and
- in November 2011, we completed a public offering in which we issued and sold a total of 21,800,000 shares of our common stock for aggregate net proceeds of \$77.3 million.

Additionally, we have obtained growth capital through loans with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation. As of December 31, 2011, the current secured credit facility with this syndicate had an outstanding principal balance of \$30.0 million and we had no further available credit. We are currently making interest-only payments on the outstanding balance of this facility, which will continue through December 2012. In January 2013, we will begin making equal monthly principal and interest payments to fully amortize the balance over a 30-month term. In connection with the establishment of our loan agreements, we have issued warrants to the lenders to purchase shares of our stock. As of December 31, 2011, 63,079 shares of common stock had been issued from the exercise of such warrants. Warrants to purchase an additional 50,331 common shares at \$12.67 per share, 254,793 common shares at \$7.0645 per share and 158,311 at \$3.79 per share, remain outstanding from our loan agreements at December 31, 2011.

### *Liquidity*

As of December 31, 2011, we had \$82.6 million in cash and cash equivalents, a decrease of \$29.6 million from \$112.2 million at December 31, 2010. This decrease was primarily due to our use of cash for operations (\$78.2 million), net purchases of marketable securities (\$22.7 million), principal payments on our previous credit facility (\$4.5 million), the second option payment we made on our Incline investment (\$3.5 million), and payments on purchases of property and equipment (\$2.7 million). These cash outflows were mostly offset by the



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\$77.3 million net proceeds received from our November 2011 public offering for 21.8 million shares of common stock, the receipt of \$3.4 million in net additional capital in December 2011 from our refinanced credit facility, and the receipt of a net \$1.4 million from stock option exercises and restricted stock unit vesting during 2011.

Our \$78.2 million use of cash in operations during 2011 represents a \$19.3 million increase from the \$58.9 million of cash used in operations during 2010. This additional use of cash during 2011 was primarily due to the \$36.4 million increased net loss we incurred during 2011 as we launched our commercial sales efforts for OFIRMEV in January 2011, partially offset by the \$15.0 million license payment made in 2010 which was not incurred in 2011. The increased net loss from our commercialization efforts in 2011 includes costs from the addition of sales representatives to market the product, along with other support personnel, and related selling and marketing costs. Correspondingly, our accounts payable and accrued liabilities increased during 2011, due primarily to the increase in commercial activities. In addition, our accounts receivable balance continues to grow as our revenue increases.

During the year ended December 31, 2011, we received net proceeds of \$77.3 million from the sale of 21.8 million shares of our common stock and net additional capital of \$3.4 million related to the refinancing of our \$30.0 million loan and security agreement. A portion of these additional funds were invested in marketable securities. As a result, we ended 2011 with a net increase of \$22.7 million in marketable securities as compared to December 31, 2010.

Our property and equipment balance at December 31, 2011, increased \$1.6 million to \$10.6 million, from \$9.0 million as of December 31, 2010. This increase was primarily due to \$3.3 million in capital equipment purchases, a portion of which was accrued but unpaid at December 31, 2011, primarily for the manufacture of OFIRMEV. These purchases were partially offset by \$1.7 million of depreciation taken during 2011. We continue to negotiate a development plan for a capacity increase at Baxter, our primary third-party manufacturer for OFIRMEV. As part of this plan, we will fund all capital equipment purchases and facility improvements necessary for the capacity increase. However, we cannot reasonably estimate the cost of this expansion at this time as the capacity increase development plan has not been completed.

### *Capital Resources*

Our cash, cash equivalents and short-term investment balances are our primary source of liquidity and currently the only sources available to us. We believe we have sufficient financial resources to fund our operations, at a minimum, for the next twelve months. However, our future funding requirements will depend on many factors, including, but not limited to:

- our ability to successfully market and sell OFIRMEV;
- our capacity to manage our commercial infrastructure and related expenses, including our hired sales and marketing personnel, and costs incurred under our agreements with third parties for warehousing, distribution, cash collection and related commercial activities;
- our execution of acquisition, in-licensing, co-promotion, or similar agreements for new products, and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our development programs for any future product candidates;
- costs associated with our ongoing intellectual property infringement lawsuits related to OFIRMEV, and any product liability or other litigation in which we may become involved;
- costs associated with any product recall or investigation into quality concerns;
- regulatory developments affecting OFIRMEV or the product candidates of our competitors;
- the level of underlying hospital demand for OFIRMEV and wholesalers' buying patterns; and
- any determination to exercise our option to acquire Incline.

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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 loan and security agreement. These financial resources may not be adequate to sustain our operations until we are able to generate significant positive cash flow from our operations and we may be required to finance future cash needs through the sale of additional equity securities, strategic collaboration agreements or debt financing. However, 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 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.

### 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, 2011 (in thousands):

	Total	Payments By Period			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-term debt obligations, including interest	\$39,359	\$ 3,114	\$27,556	\$ 8,689	\$ —
Third-party manufacturing obligations <sup>(1)</sup>	39,533	14,397	22,053	3,083	—
Operating leases <sup>(2)</sup>	1,886	1,065	817	4	—
Manufacturing capacity upgrades <sup>(3)</sup>	—	—	—	—	—
Other purchase obligations <sup>(4)</sup>	3,094	1,919	1,175	—	—
Incline transaction <sup>(5)</sup>	—	—	—	—	—
License obligations <sup>(6)</sup>	—	—	—	—	—
Total <sup>(7)</sup>	<u>\$83,872</u>	<u>\$20,495</u>	<u>\$51,601</u>	<u>\$11,776</u>	<u>\$ —</u>

<sup>(1)</sup> We have contracted with third-party manufacturers for the commercial supply of OFIRMEV. Under these agreements, we are required to purchase a certain minimum number of vials each year during the terms of the contracts. The amounts presented represent our estimates of the minimum required expenditures under these agreements; however, the ultimate liability for these obligations may be reduced if one or more of our suppliers fails or declines to supply a sufficient quantity of OFIRMEV in accordance with our purchase orders.

<sup>(2)</sup> The amounts presented represent commitments for minimum lease payments related to leases of office space and certain equipment under non-cancelable operating leases.

<sup>(3)</sup> We continue to negotiate the development plan for an increase in manufacturing capacity at Baxter, our primary third-party manufacturer for OFIRMEV, whereby we will fund all facility improvements under the development plan. In addition, upon the termination of our arrangement with Baxter, 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 costs at this time and therefore have not included these obligations in the amounts presented.

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- (4) Includes purchase commitments for capital expenditures related to our capacity increase at Baxter and other purchase obligations for services at fixed minimum costs.
- (5) Under our option agreement with Incline, we may acquire Incline for an amount not to exceed \$228.0 million, plus payment of an additional amount not to exceed \$57.0 million upon FDA approval of IONSYS. Further, we may elect to extend the second option period for two additional three-month periods upon the payment of \$2.5 million to Incline for each period. We are unable to estimate with certainty the timing and potential of these payments as they are dependent upon certain events and circumstances which may or may not occur. Therefore, we have not included these obligations in the amounts presented.
- (6) Under our license agreement with BMS, we may be required to make additional future payments up to a total of \$25.0 million upon the achievement of certain levels of net sales of OFIRMEV. We are also required to pay royalties on any net sales of OFIRMEV under the agreement and are subject to annual minimum royalty obligations. 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 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. Further, our minimum royalty obligations are not included in the table as we cannot determine the extent, if any, we will be required to pay as our obligation may be offset by payments from other parties.
- (7) We also 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.

### *Off-Balance Sheet Arrangements*

We had no off-balance sheet arrangements as of December 31, 2011.

### **Recent Accounting Pronouncements**

See Note 2 to the Notes to Financial Statements in Item 8 below for further discussion of recent accounting pronouncements.

### **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. As of December 31, 2011, our holdings consisted of investments in money market funds, debt obligations of government agencies, municipalities, commercial paper and certificates of deposit. These investments were 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 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

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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, 2011 (in thousands):

	<u>Amortized Cost Basis</u>	<u>Fair Value</u>
Cash equivalents	\$ 80,735	\$ 80,735
Available-for-sale marketable securities	\$ 44,616	\$ 44,618

### **Debt**

Our current loan and security agreement has a fixed interest rate. Consequently, we do not have significant interest rate cash flow exposure on our debt. The principal balance of the loan under the agreement at December 31, 2011 was \$30.0 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. We believe we were in compliance with all such covenants under the agreement as of December 31, 2011.

**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. as of December 31, 2011 and 2010, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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 Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2011, 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 13, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
March 13, 2012

**CADENCE PHARMACEUTICALS, INC.**  
**BALANCE SHEETS**  
**(in thousands, except share and per share data)**

	December 31,	
	2011	2010
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 82,609	\$ 112,175
Investments in marketable securities	44,618	21,966
Restricted cash	450	150
Accounts receivable, net	2,703	—
Inventory	1,388	485
Prepaid expenses	1,071	1,232
Other current assets	90	36
Total current assets	<u>132,929</u>	<u>136,044</u>
Property and equipment, net	10,569	8,986
Intangible assets, net	13,433	15,000
Restricted cash	190	190
Other assets	7,039	3,566
Total assets	<u>\$ 164,160</u>	<u>\$ 163,786</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,801	\$ 3,416
Accrued liabilities	10,945	7,286
Deferred revenue	1,291	—
Current portion of long-term debt, less discount of \$- and \$429, respectively	—	4,023
Total current liabilities	<u>16,037</u>	<u>14,725</u>
Long-term debt, less current portion and discount of \$1,304 and \$894, respectively	28,696	24,654
Other long-term liabilities	117	447
Total liabilities	<u>44,850</u>	<u>39,826</u>
Commitments and contingencies (Note 8)		
Stockholders' equity :		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2011 and 2010, respectively	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized, 85,511,607 shares and 63,107,361 shares issued and outstanding at December 31, 2011 and 2010, respectively	9	6
Additional paid-in capital	485,982	397,616
Accumulated other comprehensive income	2	—
Accumulated deficit	<u>(366,683)</u>	<u>(273,662)</u>
Total stockholders' equity	<u>119,310</u>	<u>123,960</u>
Total liabilities and stockholders' equity	<u>\$ 164,160</u>	<u>\$ 163,786</u>

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

**CADENCE PHARMACEUTICALS, INC.**  
**STATEMENTS OF OPERATIONS**  
**(in thousands, except per share data)**

	Year Ended December 31,		
	2011	2010	2009
Revenues:			
Product revenue, net	\$ 11,486	\$ —	\$ —
License revenue	5,210	—	—
Total net revenues	<u>16,696</u>	<u>—</u>	<u>—</u>
Costs and expenses:			
Cost of product sales	12,406	—	—
Amortization of patent license	1,567	—	—
Research and development	8,885	13,757	19,464
Selling, general and administrative	81,504	39,347	24,620
Other	1,076	1,813	413
Total costs and expenses	<u>105,438</u>	<u>54,917</u>	<u>44,497</u>
Loss from operations	(88,742)	(54,917)	(44,497)
Other (expense) income:			
Interest income	136	106	182
Interest expense	(4,424)	(2,144)	(1,137)
Other income (expense)	9	312	(39)
Total other expense, net	<u>(4,279)</u>	<u>(1,726)</u>	<u>(994)</u>
Loss before income tax	<u>(93,021)</u>	<u>(56,643)</u>	<u>(45,491)</u>
Net loss	<u>\$ (93,021)</u>	<u>\$ (56,643)</u>	<u>\$ (45,491)</u>
Basic and diluted net loss per share <sup>(1)</sup>	<u>\$ (1.41)</u>	<u>\$ (1.09)</u>	<u>\$ (0.93)</u>
Shares used to compute basic and diluted net loss per share <sup>(1)</sup>	<u>66,075</u>	<u>52,042</u>	<u>48,754</u>

<sup>(1)</sup> As a result of the issuance of common stock pursuant to public offerings in the fourth quarter of 2011 and 2010, 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.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands, except per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount					
<b>Balance at December 31, 2008</b>	<b>38,364</b>	<b>\$ 4</b>	<b>\$ 197,965</b>	<b>\$ —</b>	<b>\$ (171,528)</b>	<b>\$ 26,441</b>	
Private placement offering of common stock, net of \$353 offering costs, in February at \$7.13 per share and warrants to purchase 6,020 shares of common stock at \$7.84 per share for \$0.125 per warrant	12,040	1	86,242	—	—	86,243	
Issuance of common stock from option exercises under equity compensation plans	81	—	115	—	—	115	
Stock-based compensation	—	—	7,755	—	—	7,755	
Net Loss	—	—	—	—	(45,491)	(45,491)	\$ (45,491)
<b>Balance at December 31, 2009</b>	<b>50,485</b>	<b>5</b>	<b>292,077</b>	<b>—</b>	<b>(217,019)</b>	<b>75,063</b>	<b>\$ (45,491)</b>
Issuance of warrants in June to purchase 255 shares of common stock at \$7.0645 per share	—	—	1,237	—	—	1,237	
Public offering of common stock, net of \$6,445 offering costs, in November and December at \$8.00 per share	12,500	1	93,554	—	—	93,555	
Issuance of common stock from option exercises and lapse of restricted stock units under equity compensation plans	122	—	235	—	—	235	
Stock-based compensation	—	—	10,513	—	—	10,513	
Net Loss	—	—	—	—	(56,643)	(56,643)	\$ (56,643)
<b>Balance at December 31, 2010</b>	<b>63,107</b>	<b>6</b>	<b>397,616</b>	<b>—</b>	<b>(273,662)</b>	<b>123,960</b>	<b>\$ (56,643)</b>
Public offering of common stock, net of \$4,448 offering costs, in November at \$3.75 per share	21,800	2	77,300	—	—	77,302	
Issuance of warrants in December to purchase 158 shares of common stock at \$3.79 per share	—	—	390	—	—	390	
Issuance of common stock from option exercises and lapse of restricted stock units under equity compensation plans	605	1	1,443	—	—	1,444	
Stock-based compensation	—	—	9,233	—	—	9,233	
Unrealized gain on marketable securities, net	—	—	—	2	—	2	\$ 2
Net Loss	—	—	—	—	(93,021)	(93,021)	(93,021)
<b>Balance at December 31, 2011</b>	<b>85,512</b>	<b>\$ 9</b>	<b>\$ 485,982</b>	<b>\$ 2</b>	<b>\$ (366,683)</b>	<b>\$ 119,310</b>	<b>\$ (93,019)</b>

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



**CADENCE PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31,		
	2011	2010	2009
<b>Operating activities</b>			
Net loss	\$ (93,021)	\$ (56,643)	\$ (45,491)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,670	758	537
(Gain) loss on disposal of assets	(66)	55	7
Impairment of long-lived assets	—	1,522	—
Inventory write-down	5,574	—	—
Adjustment to estimate of impairment of long-lived assets	—	—	(181)
Impairment of available-for-sale securities	—	—	45
Stock-based compensation	9,233	10,513	7,755
Non-cash interest expense	49	32	26
Amortization of intangible assets	1,567	—	—
Amortization of discount on note payable	409	373	219
Accretion of premiums on available-for-sale securities, net of accretion of discounts	5	29	130
Changes in operating assets and liabilities:			
Accounts receivable	(2,703)	—	—
Prepaid expenses and other current assets	104	(585)	(444)
Intangible assets	—	(15,000)	—
Inventory	(6,477)	(485)	—
Accounts payable	360	653	(1,930)
Deferred revenue	1,291	—	—
Accrued liabilities and other liabilities	3,853	(82)	(2,721)
Net cash used in operating activities	<u>(78,152)</u>	<u>(58,860)</u>	<u>(42,048)</u>
<b>Investing activities</b>			
Purchases of marketable securities	(82,681)	(24,201)	(10,738)
Maturities of marketable securities	60,006	8,250	4,575
Payment for option purchase right	(3,500)	(3,500)	—
Restricted cash	(300)	1,348	1,046
Purchases of property and equipment	(2,733)	(3,754)	(3,267)
Proceeds from the sale of property and equipment	66	3	—
Net cash used in investing activities	<u>(29,142)</u>	<u>(21,854)</u>	<u>(8,384)</u>
<b>Financing activities</b>			
Proceeds from issuance of common stock	78,746	93,790	86,358
Borrowings under debt agreements, net of fees	3,434	29,591	—
Principal payments under debt agreements	(4,452)	(6,351)	(7,694)
Net cash provided by financing activities	<u>77,728</u>	<u>117,030</u>	<u>78,664</u>
Net (decrease) increase in cash and cash equivalents	<u>(29,566)</u>	<u>36,316</u>	<u>28,232</u>
Cash and cash equivalents at beginning of period	<u>112,175</u>	<u>75,859</u>	<u>47,627</u>
Cash and cash equivalents at end of period	<u>\$ 82,609</u>	<u>\$ 112,175</u>	<u>\$ 75,859</u>
<b>Supplemental disclosures</b>			
Issuance of warrants in connection with loan and security agreement	\$ 390	\$ 1,237	\$ —
Shares in unconsolidated entity acquired in option purchase agreement	\$ —	\$ 500	\$ —
Property and equipment purchases in accounts payable and accrued expenses	\$ 891	\$ 371	\$ 1,101
Cash paid for interest and fees	\$ 4,311	\$ 1,986	\$ 814

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

**CADENCE PHARMACEUTICALS, INC.**  
**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 acquiring, in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. In March 2006, the Company in-licensed the exclusive U.S. and Canadian rights to OFIRMEV<sup>®</sup>, an intravenous formulation of acetaminophen, from Bristol-Myers Squibb Company (“BMS”). In November 2010, the Food and Drug Administration (“FDA”) approved the Company’s New Drug Application (“NDA”) for OFIRMEV for the management of mild to moderate pain, moderate to severe pain with adjunctive opioid analgesics, and the reduction of fever in adults and children two years of age and older. In January 2011, the Company commenced commercial sales of the product in the U.S., and therefore it is no longer considered 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 revenue and 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. Examples of such estimates include, but are not limited to, inventory obsolescence and valuation, restructuring liabilities, stock-based compensation, and commitments and contingencies. 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.

***Reclassifications***

The Company has reclassified certain prior period amounts to conform to the current period presentation. Specifically, it has consolidated its sales and marketing expense and its general and administrative expense into a single selling, general and administrative expense category. This reclassification had no impact on the net loss from operations or stockholders’ equity as previously reported.

***Revenue Recognition***

The Company recognizes revenue when there is persuasive evidence that an arrangement exists, title has passed, collection is reasonably assured and the price is fixed or determinable. It sells OFIRMEV mostly to wholesalers who in-turn sell the product to hospitals and other end-user customers. Sales to wholesalers provide for selling prices that are fixed on the date of sale, although the Company offers certain discounts to group purchasing organizations and governmental programs. The wholesalers take title to the product, bear the risk of loss of ownership, and have economic substance to the inventory. Further, the Company has no significant obligations for future performance to generate pull-through sales, however it does allow wholesalers to return product that is damaged or received in error. In addition, the Company allows for product to be returned beginning six months prior to, and ending twelve months following, product expiration. As OFIRMEV is the Company’s first and only commercially available product and there is a limited amount of product return data, the Company does not believe it has sufficient sales and returns history at this time to accurately predict product returns from its wholesaler distribution channel. Therefore, the Company is deferring the recognition of revenue until the wholesalers sell OFIRMEV to hospitals or other end-user customers. It will continue to defer revenue

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

recognition until the point at which it has obtained sufficient sales history to accurately estimate returns from the wholesalers. Shipments of product that are not recognized as revenue are treated as deferred revenue until evidence exists to confirm that pull-through sales to hospitals or other end-user customers have occurred.

The Company records certain sales reserves and allowances as a reduction to gross revenue and deferred revenue, as applicable. These reserves and allowances include distribution service fees, a prompt payment reserve, a group purchasing discount and chargeback reserve, and discounts to governmental programs, as applicable. Distribution service fees arise from contractual agreements the Company has with certain wholesalers for distribution services they provide with respect to OFIRMEV. These fees are generally a fixed percentage of the price of the product purchased by these wholesalers. The prompt payment reserve is based upon cash discounts the Company offers certain wholesalers as an incentive to meet certain payment terms. It accounts for these cash discounts at the time the sale is made to the wholesalers and reduces its accounts receivable accordingly. The group purchasing discount and chargeback reserve is based upon contracted discounts the Company provides to members of certain purchasing groups. The Company estimates the sales through its wholesalers to these group purchasing organizations and accrues for the chargebacks it anticipates from its wholesalers for the difference between the current retail price and the reduced price paid by the members of the group purchasing organizations. A group purchasing organization fee the Company incurs for these transactions is also recorded at the time of sale. The Company also provides governmental programs a predetermined discount that is recorded at the time of sale.

Revenue from the Company's data license agreement is recognized upon delivery of the goods and services provided, based upon the consideration allocated to each deliverable. The Company allocates the consideration to each deliverable based upon its review of the agreement pursuant to multiple-element arrangement guidance. See Note 9 for further discussion.

***Accounts Receivable***

The Company extends credit to its customers in the normal course of business based upon an evaluation of the customer's credit history, financial condition and other factors. Trade accounts receivable are recorded on gross sales to wholesalers, net of allowances for prompt payment and other discounts, chargebacks and doubtful accounts. Wholesaler distribution fees are recorded as accounts payable and accrued liabilities. Estimates of allowances for doubtful accounts are determined by evaluating individual customer circumstances, historical payment patterns, length of time past due and economic and other factors. As of December 31, 2011 and December 31, 2010, the Company had no reserves for doubtful accounts on its balance sheets. Further, during the years ended December 31, 2011, 2010 and 2009, no charges were incurred to reserve or write-off past due accounts.

***Fair Value Reporting***

The Company's financial instruments consist of cash and cash equivalents, marketable securities, restricted cash, trade receivables and payables, an option purchase right, equity securities of an unconsolidated privately-held entity, 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, trade receivables and payables, accrued liabilities and long term debt are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The Company's option purchase right and equity securities of an unconsolidated privately-held entity have been initially valued based upon the transaction price under the cost method of accounting. These assets are subject to fair value adjustments in certain circumstances, such as when there is evidence of impairment. The fair value of marketable securities is based upon market prices quoted on the last day of the fiscal period.

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

Current accounting guidance defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and requires certain disclosures about 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.

The following tables present further detail of the financial instruments carried at fair value on the Company's balance sheet as of December 31, 2011 and 2010. The tables do not include assets and liabilities which are measured at historical cost or on any basis other than fair value (in thousands):

<u>Description</u>	<u>Balance at December 31, 2011</u>	<u>Fair Value Measurements as of December 31, 2011</u>		
		<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ 74,389	\$ 74,389	\$ —	\$ —
Debt instruments—Corporate debt obligations	6,346	—	6,346	—
Investments in marketable securities—short-term:				
Debt instruments—Corporate debt obligations	37,394	—	37,394	—
Debt instruments—Municipal debt obligations	6,224	—	6,224	—
Certificates of deposit	1,000	—	1,000	—
Assets at fair value	<u>\$ 125,353</u>	<u>\$ 74,389</u>	<u>\$50,964</u>	<u>\$ —</u>

<u>Description</u>	<u>Balance at December 31, 2010</u>	<u>Fair Value Measurements as of December 31, 2010</u>		
		<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ 107,611	\$107,611	\$ —	\$ —
Debt instruments—Corporate debt obligations	4,500	—	4,500	—
Investments in marketable securities—short-term:				
Debt instruments—Municipal debt obligations	15,466	—	15,466	—
Debt instruments—Corporate debt obligations	5,500	—	5,500	—
Certificates of deposit	1,000	—	1,000	—
Assets at fair value	<u>\$ 134,077</u>	<u>\$107,611</u>	<u>\$26,466</u>	<u>\$ —</u>

The Company's level 2 financial instruments are valued using market prices on less active markets and model-derived valuations with observable valuation inputs such as interest rates and yield curves. The Company obtains the fair value of Level 2 financial instruments from a third-party pricing service, which the Company validates through independent valuation testing and review of portfolio valuations provided by the Company's investment managers.

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

***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, 2011 and 2010, the Company's cash equivalents were \$80,735,000 and \$112,111,000, 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. Available-for-sale securities are recorded at fair value, based on current market valuations. Unrealized holding gains and losses on available-for-sale securities are excluded from earnings and are reported as a separate component of other comprehensive income until realized. Realized gains and losses are included in non-operating other income (expense) on the statement of operations 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 year ended December 31, 2009 the Company recorded an impairment charge to reduce the value of an available-for-sale equity security by \$45,000 as the market value was significantly below the security's carrying value. No such charges were incurred for the years ended December 31, 2011 and 2010. See Note 3 for further discussion.

***Concentration Risk***

***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. To date, the Company has not experienced any material realized losses on its cash, cash equivalents, restricted cash and marketable securities.

***Manufacturing.*** The Company depends on an outsourced manufacturing strategy for its products. Currently, it has a primary third-party manufacturer and a supplemental manufacturer approved for the production of OFIRMEV. Further, the Company relies upon a single source for the active pharmaceutical ingredient for OFIRMEV at both third-party manufacturers.

***Customers.*** The Company has entered into distribution agreements with three major pharmaceutical wholesalers to supply OFIRMEV across the U.S. through their distribution centers and a majority of the Company's sales are to these customers. These customers represented approximately 93% of the Company's product revenue for 2011 and approximately 92% of the Company's accounts receivable balance at December 31, 2011. However, these wholesalers sell OFIRMEV to hospitals and other end-user customers and as of December 31, 2011, approximately 2,200 accounts had ordered OFIRMEV. See Note 12 for further detail of our significant customers.

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

***Inventories***

The Company states its inventories at the lower of cost or market. The Company uses a combination of standard and actual costing methodologies to determine its cost basis for its inventories. These methodologies approximate actual costs on a first-in, first-out basis. In addition to stating inventory at the lower of cost or market, the Company also evaluates inventory each period for excess quantities and obsolescence. This evaluation includes identifying those items specifically identified as obsolete and reserving them, analyzing forecasted demand versus quantities on hand and reserving for the excess, and identifying other specific reserves. For 2011, the Company recorded a charge for inventory losses of \$5,574,000 in cost of sales to write-down certain inventory manufactured to its estimated net realizable value. The product in question was placed on indefinite hold pending the outcome of an investigation into unidentified particulate matter observed during routine product stability testing. The charge is based upon the Company's best estimate of the value it will realize from the sale, if any, of the product and is being recorded due to uncertainty as to the amount of time that may be required to complete the investigation and whether the product will have sufficient remaining shelf life or otherwise be saleable after the investigation is completed.

***Royalty and License Payments***

Pursuant to the terms of its license agreement with BMS, the Company is required to make royalty payments based upon net sales of OFIRMEV, subject to annual minimums. The Company will accrue for these payments as the product is sold, or otherwise deemed obligated. Additionally, the Company paid \$15,000,000 under the license agreement upon the NDA approval of OFIRMEV in November 2010 and may be required to make future milestone payments of up to \$25,000,000 based the achievement of certain levels of net sales. The Company has capitalized the \$15,000,000 payment as an intangible asset on its balance sheet and is amortizing this balance over the estimated useful life of the licensed patents. As of December 31, 2011, the Company had amortized an aggregate \$1,567,000 of the payment and the estimated aggregate amortization expense of the payment for each of the five succeeding fiscal years is approximately \$1,343,000. The Company will accrue for future milestone payments as they are anticipated and amortize the payments over the period in which the milestone is achieved.

***Advertising Expense***

The Company records the cost of its advertising efforts when services are performed or goods are delivered. The Company incurred advertising costs of approximately \$2,181,000 and \$828,000, respectively, for the years ended December 31, 2011 and 2010. No advertising expense was incurred during the year ended December 31, 2009. As of December 31, 2011 and 2010, the Company capitalized \$24,000 and \$30,000, respectively, of advertising costs in prepaid expenses.

***Shipping and Handling Costs***

The costs incurred by the Company for shipping and handling are classified as cost of product sales. The Company does not charge its customers shipping and handling costs.

***Property and Equipment***

Property and equipment, including leasehold improvements, are stated at cost. 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.

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

For the years ended December 31, 2011, 2010 and 2009, the Company recorded depreciation expense of \$1,670,000, \$758,000 and \$537,000, respectively.

***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 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 2010, the Company recorded a charge of \$1,522,000 due to the modification of the design of the planned second production line for OFIRMEV, resulting in the partial cancellation of a capital equipment order for which the Company had identified an alternative supplier. During 2009, the Company recorded an adjustment to a previously incurred impairment charge related to the discontinuation of its omigagan pentahydrochloride development program, reducing the charge by \$181,000, as actual costs incurred in disposing of the assets were less than anticipated. The impairment charge and adjustment are included in "Other" operating expenses on the Company's statement of operations for the years ended December 31, 2010 and 2009, respectively. No similar charges were incurred during the year ended December 31, 2011.

***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.

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

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.

**Stock-Based Compensation**

The Company has stock-based compensation plans, which are described in Note 11. As of December 31, 2011, the Company had issued both stock option awards and restricted stock units under its stock-based compensation plans.

**Stock option awards.** Stock options are 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, 2011, 2010 and 2009, to determine the fair value of stock options granted during each period:

	Year Ended December 31,		
	2011	2010	2009
Risk free interest rates	2.2%	2.7%	2.2%
Expected life in years	6.2 years	5.9 years	6.0 years
Expected dividend yield	0.0%	0.0%	0.0%
Expected volatility	73.9%	76.3%	71.6%

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 has historically been calculated using the simplified method, as prescribed by the Securities and Exchange Commission ("SEC"), due to the lack of relevant historical exercise data. In addition, due to the Company's limited historical stock price volatility data, the estimated volatility has historically been calculated by incorporating the historical volatility of comparable companies. In 2011, the Company began to incorporate the historical stock price volatility and the implied volatility of its exchanged traded options in determining the expected volatility. 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, 2011, 2010 and 2009 at \$5.67, \$5.99 and \$5.99, 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. The weighted-average grant date fair value of the RSUs granted in 2010 and 2009 was \$10.38 and \$10.91 respectively. There were no RSUs granted in 2011.

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



**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

that is ultimately expected to vest. Hence, the gross expense is reduced for estimated forfeitures and adjusted for the probability of achieving performance criteria. If awards are forfeited prior to vesting, all previous expense recognized is recovered during the period in which the forfeiture occurs.

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

	Year Ended December 31,		
	2011	2010	2009
Cost of product sales	\$ 297	\$ —	\$ —
Research and development	2,308	3,058	2,577
Selling, general and administrative	6,628	7,455	5,178
Total stock-based compensation expense included in loss from operations	<u>\$9,233</u>	<u>\$10,513</u>	<u>\$7,755</u>

The compensation expense related to unvested stock options and RSUs not yet recognized was approximately \$15,580,000 at December 31, 2011. This expense is expected to be recognized over a weighted-average period of approximately 35 months. The total fair value of shares vested during the years ended December 31, 2011, 2010 and 2009 was \$9,852,000, \$9,273,000 and \$6,546,000, 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). The balance of accumulated other comprehensive income at December 31, 2011 was comprised of the net unrealized net holding gains on the Company's investments in marketable securities. There was no similar accumulated other comprehensive income or loss at December 31, 2010. See Note 3 for further detail of the unrealized holdings gains and losses on the Company's investments in marketable securities.

***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 2011, 2010 and 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, 2011, 2010 and 2009 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 (1) 21,800,000 common shares issued pursuant to a public offering in the fourth quarter of 2011; (2) 12,500,000 common shares issued pursuant to a public offering in the fourth quarter of 2010; and (3) 12,039,794 common shares issued pursuant to a private placement in the first quarter of 2009. 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.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

The following is a reconciliation of the basic and diluted shares for the periods presented (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Shares for basic and dilutive net loss per share:			
Weighted average common shares outstanding	66,075	52,043	48,841
Weighted average unvested common shares subject to repurchase	—	(1)	(87)
Denominator for basic and diluted earnings per share	<u>66,075</u>	<u>52,042</u>	<u>48,754</u>

At December 31, 2011, 2010 and 2009, options, restricted stock units and warrants totaling approximately 14,457,000 shares, 13,460,000 shares and 11,446,000 shares, respectively, were excluded from the calculation as their effect would have been anti-dilutive.

**Recent Accounting Pronouncements**

In June 2011, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2011-05, *Comprehensive Income (Topic 220)—Presentation of Comprehensive Income*. ASU 2011-05 amends the presentation of comprehensive income to allow an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both options, the entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. The guidance eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders’ equity. In December 2011, the FASB issued ASU 2011-12 which defers certain provisions of ASU 2011-05. Under ASU 2011-12, the provision to require entities to present reclassification adjustments out of accumulated other comprehensive income by component in both the statement of operations and the statement of equity was deferred indefinitely. During the deferral period, entities will be required to comply with all existing requirements for reclassification adjustments. The Company adopted these standards on January 1, 2012, which did not have an impact on the Company’s financial results or disclosures, but will have an impact on the presentation of comprehensive income.

**3. Investments in Marketable Securities**

In accordance with the Company’s investment policy, it has invested funds in marketable debt securities. 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, 2011 and December 31, 2010 consisted of the following (in thousands):

At December 31, 2011	Amortized Cost Basis	Other-than- temporary Impairments	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Available-for-sale:					
Debt instruments—Corporate debt obligations	\$ 37,392	\$ —	\$ 3	\$ (1)	\$ 37,394
Debt instruments—Municipal debt obligations	6,224	—	—	—	6,224
Certificates of deposit	1,000	—	—	—	1,000
	<u>\$ 44,616</u>	<u>\$ —</u>	<u>\$ 3</u>	<u>\$ (1)</u>	<u>\$ 44,618</u>

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

At December 31, 2010	Amortized Cost Basis	Other-than- temporary Impairments	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
<b>Available-for-sale:</b>					
Debt instruments—Municipal debt obligations	\$ 15,466	\$ —	\$ —	\$ —	\$ 15,466
Debt instruments—Corporate debt obligations	5,500	—	—	—	5,500
Certificates of deposit	1,000	—	—	—	1,000
	<u>\$ 21,966</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 21,966</u>

Investments by contractual maturity are as follows (in thousands):

	December 31, 2011		December 31, 2010	
	Cost	Fair Value	Cost	Fair Value
Due or callable in one year or less	\$44,616	\$ 44,618	\$21,966	\$ 21,966
Due after one year	\$ —	\$ —	\$ —	\$ —

As of December 31, 2011, the Company held two investments in an unrealized loss position, all of which have been in such a position for less than 12 months. There were no investments in unrealized loss positions as of December 31, 2010.

**4. Selected Financial Statement Data**

	As of December 31,	
	2011	2010
<b>Inventory (in thousands):</b>		
Raw materials	\$ 96	\$ 68
Finished goods	1,292	417
	<u>\$ 1,388</u>	<u>\$ 485</u>
<b>Property and equipment (in thousands):</b>		
Manufacturing equipment	\$ 6,925	\$ 4,016
Leasehold improvements	1,610	1,610
Computer equipment and software	1,629	1,505
Furniture and fixtures	458	455
Construction-in-process	3,965	3,813
	14,587	11,399
Less accumulated depreciation	(4,018)	(2,413)
Total	<u>\$10,569</u>	<u>\$ 8,986</u>
<b>Accrued liabilities (in thousands):</b>		
Accrued personnel costs	\$ 6,896	\$ 3,987
Accrued manufacturing costs and equipment purchases	1,613	562
Other accrued liabilities	2,436	2,737
Total	<u>\$10,945</u>	<u>\$ 7,286</u>

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

**5. Investment in Incline**

On June 21, 2010, the Company entered into an option agreement (the “Option Agreement”) with Incline Therapeutics, Inc. (“Incline”), a privately held specialty pharmaceutical company, pursuant to which the Company obtained an exclusive, irrevocable option to acquire Incline during two option periods, and has additional rights after the expiration of the second period. Incline is developing IONSYS™ (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery. As consideration for the option, the Company paid Incline a \$3,500,000 upfront option fee in June 2010 and made a second payment of \$3,500,000 in September 2011 upon Incline’s receipt of the second tranche of its Series A financing. The Company is currently in the second of two option periods, which extends until the earliest to occur of (1) 30 days after the date on which Incline submits a supplemental NDA for IONSYS to the FDA, (2) 30 days after the filing of an initial public offering by Incline, or (3) 42 months after the effective date of the option (December 21, 2013). During this second option period, the Company may acquire Incline for an amount not to exceed \$228,000,000, plus payment of an additional amount not to exceed \$57,000,000 upon FDA approval of IONSYS. The Company has an exclusive right of first negotiation to acquire Incline for the six-month period following the expiration of the second option period. In addition, the Company may elect to extend the second option period for two additional three-month periods upon the payment of \$2,500,000 to Incline for each period. Incline will remain primarily responsible for the development of IONSYS. However, the Company and Incline have formed a joint development committee to oversee the global development and regulatory approval for the IONSYS product candidate.

The Company has determined that Incline is a variable interest entity (“VIE”). However, because it will not absorb a disproportionate amount of Incline’s expected losses or receive a disproportionate amount of Incline’s expected residual returns, the Company is not the primary beneficiary of this entity at this time. Further, Cadence will have no oversight of the day-to-day operations of Incline, nor does it have sufficient rights or voting representation to influence the operating or financial decisions of Incline. Additionally, the Company was not a founder of Incline and has no additional equity or funding requirements in future financings or otherwise. Therefore, the Company is not required to consolidate Incline into its financial statements. This consolidation status could change in the future if the option agreement is exercised, or if other changes occur in the relationship between the Company and Incline. Frazier Healthcare VI, L.P. owns approximately 22.4% of Incline’s Series A Preferred Stock. Alan D. Frazier, one of the Company’s directors, has an ownership interest in Frazier Healthcare VI, L.P., and is a member of the general partner of the entity that serves as general partner of Frazier Healthcare VI, L.P.

In consideration of the Company’s expenditure of funds in connection with conducting due diligence on IONSYS, the Company received \$500,000 of Incline Series A preferred stock, or 500,000 shares, on terms generally consistent with Incline’s other Series A preferred stock investors. The Company has valued the investment in the option, and the shares received from the due diligence, using the cost method and classified these investments as Level 3 in the fair value hierarchy. At the time of the first option payment in June 2010, the Company assigned \$500,000 to the preferred stock and \$3,000,000 to the option. The value of the second option payment in September 2011 was fully applied to the option, resulting in an aggregate option value of \$6,500,000. Under the cost method, the fair value of the investment is not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment. The Company has reviewed the value allocated from the June 2010 and September 2011 payments and is not aware of any such adverse events which would be expected to negatively influence these values at December 31, 2011. As a result, no fair value estimate has been prepared with respect to this investment as the costs associated with an independent evaluation would be excessive and the available information on which to base such an assessment is both limited and highly subjective. Therefore, there have been no reductions to the aggregate \$7,000,000

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

carrying value of the investments, which represents the Company's maximum loss exposure to Incline at December 31, 2011. Both assets are recorded as other long-term assets on the Company's balance sheets at December 31, 2011 and December 31, 2010, respectively.

## 6. Restructuring and Impairment Charges

In November 2011, the Company commenced a restructuring of its workforce to focus its resources on the commercialization of OFIRMEV and reduce program costs not directly associated with such efforts. Additionally, in March 2009, the Company announced its decision to discontinue the development of its omiganan pentahydrochloride product candidate and implemented a corporate restructuring in order to reduce, and eventually eliminate, costs associated with the program.

As a result of the 2011 restructuring, the Company recorded one-time employee termination charges of \$1,142,000 in connection with the termination of 17 employees. The discontinuation of the omiganan pentahydrochloride program in 2009 resulted in charges of \$651,000 in connection with the termination of 11 employees. The Company also recorded impairment charges in the fourth quarter of 2008 of \$2,353,000 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. The Company recorded adjustments to this impairment charge in 2009, reducing the charge by an aggregate \$181,000 as actual costs incurred in disposing of the assets were less than anticipated. All such charges and credits were recorded in "Other" operating expense for the periods indicated.

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

	Year Ended December 31,		
	2011	2010	2009
Beginning restructuring liability	\$ —	\$ —	\$ —
Severance and termination charges incurred	1,142	—	651
Adjustments to severance and termination charges	—	—	(64)
Severance and termination disbursements	(211)	—	(587)
Ending restructuring liability	<u>\$ 931</u>	<u>\$ —</u>	<u>\$ —</u>

The balance of the restructuring liability at December 31, 2011 is anticipated to be fully distributed in 2012.

## 7. Loan and Security Agreement

In December 2011, the Company entered into a Second Amended and Restated Loan and Security Agreement (the "Second Amended Agreement") with Oxford Finance LLC ("Oxford"), Silicon Valley Bank ("SVB") and General Electric Capital Corporation ("GECC") (collectively, the "Lenders"). The Second Amended Agreement amends and restates the Company's previous Amended and Restated Loan and Security Agreement (the "Restated Agreement") entered in June 2010 with the Lenders, and provided the Company with \$3,434,000 of additional net capital after deducting a \$954,000 term loan final payment paid under the Restated Agreement and customary closing fees and expenses of \$63,000 paid in connection with the closing of the Second Amended Agreement. The interest rate under the Second Amended Agreement is 10.99% and the Company will be required to make a final payment of 6% of the total advance at the termination of the loan.

Pursuant to the terms of the Second Amended Agreement, the Company will make interest only payments through December 2012, and in January 2013, will begin to make equal monthly principal and interest payments to fully amortize the balance over the remaining 30-month term. The Company issued warrants to purchase

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

158,311 shares of the Company's common stock to the Lenders in connection with the Second Amended Agreement at an exercise price \$3.79 per share. The warrants are immediately exercisable, and excluding certain mergers or acquisitions, will expire on the seven-year anniversary of the date of issuance. The Company determined the relative fair value of these warrants, as detailed below, and has classified the warrants as equity, recognizing the cost as a discount on the loan issuance. The credit facility contains customary default and acceleration provisions and is secured by the Company's assets, excluding intellectual property. The Company was required to make a negative pledge of its intellectual property, which generally prohibits the Company from granting liens on its intellectual property. Under the terms of the Second Amended 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 Second Amended Agreement), the lenders may declare all outstanding amounts due and payable under the Second Amended Agreement. As of December 31, 2011, the Company believed it was in compliance will all covenants under the Second Amended Agreement.

The Company determined that the terms of Second Amended Agreement were not substantially different than the Restated Agreement and hence has accounted for the transaction as a loan modification. As such, the fair value the warrants issued in connection with the Second Amended Agreement and the carrying value of the issuance costs and discount related to the Restated Agreement were aggregated and are being amortized to interest expense throughout the life of the Second Amended Agreement using an effective interest rate of 15.31%.

In connection with the establishment of the \$30,000,000 credit facility in June 2010 under the Restated Agreement, the outstanding balance of the Company's previous \$15,000,000 credit facility established in 2007 was paid in full, including accrued interest, and a \$375,000 term loan final payment. The transaction was accounted for as a loan extinguishment and upon the repayment of the \$15,000,000 facility, the Company recorded a charge of approximately \$145,000 in the second quarter of 2010 to (1) fully amortize the balance of the loan discount and related issuance costs and (2) fully accrue the term loan final payment. The warrants issued and the upfront fees paid in connection with the Restated Agreement were recognized as a discount on the loan issuance and the legal and related expenses were recognized as debt issuance costs on the Company's balance sheets. The carrying value of these costs at the time of the loan modification in December 2011 were aggregated with the relative fair value of the warrants issued in connection with the Second Amended Agreement and are being amortized throughout the life of the Second Amended Agreement as noted above.

As of December 31, 2011 and 2010, the aggregate outstanding principal balance of the loans included on the Company's balance sheets for each period was \$30,000,000. Future maturities and interest payments under the Company's Second Amended Agreement as of December 31, 2011 were as follows (in thousands):

2012	\$ 3,114
2013	13,778
2014	13,778
2015	8,689
2016	—
Total future payments	39,359
Less amount representing interest and fees	<u>(9,359)</u>
Gross balance of long-term debt	30,000
Less unamortized discount	<u>(1,304)</u>
Total present value of long-term debt	<u>\$28,696</u>

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

**Warrants**

In connection with the establishment of the Company's \$15,000,000 credit facility with the Lenders in 2007, 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 \$474,000 under the Black-Scholes valuation model 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, 2011, all of these warrants were outstanding.

In connection with the Restated Agreement, the Company issued three fully exercisable warrants to the Lenders in June 2010 to purchase an aggregate of 254,793 shares of the Company's common stock at an exercise price of \$7.0645 per share, expiring June 18, 2017. The Company classified the warrants as equity and determined their relative fair value to be \$1,237,000, using the Black-Scholes valuation model. The value of the warrants was recorded as a discount to the loan and is currently being amortized to interest expense over the term of the Second Amended Agreement pursuant to the loan modification. The warrants were valued using the following assumptions: risk-free interest rate of 2.7%; dividend yield of 0.0%; expected volatility of 76.5%; and a contractual term of seven years. As of December 31, 2011, all warrants related to the Restated Agreement were outstanding.

In connection with the Second Amended Agreement, the Company issued four exercisable warrants to the lenders in December 2011 to purchase an aggregate of 158,311 shares of the Company's common stock at an exercise price of \$3.79 per share, expiring December 22, 2018. The Company classified the warrants as equity and determined their relative fair value to be \$390,000, 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 1.4%; dividend yield of 0.0%; expected volatility of 72.4%; and a contractual term of seven years. As of December 31, 2011, all warrants related to the Second Amended Agreement were outstanding.

**8. Commitments and Contingencies**

**Leases**

In May 2006, the Company entered into a six-year operating lease for office space. In December 2011, the Company amended the lease to reduce the monthly rent charge, extend the lease term and terminate a portion of the lease, returning space to the lessor. Pursuant to the terms of the amended agreement, the basic monthly per square foot fee will be reduced commencing in April 2012 and the Company will return a portion of the leased space in September 2012. The lease will expire in December 2013 with no option to extend the term.

As security for the initial lease, a letter of credit in the initial amount of \$1,581,000 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 was eligible to be reduced by 22% on each of the first four anniversaries of the commencement of the lease and as of December 31, 2011, the letter of credit had been reduced by \$1,391,000 in accordance with the agreement and the related restricted cash had been 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 at December 31, 2011 and 2010, was \$190,000.

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

The Company also leases certain office equipment under operating leases with original terms that range from one to four years and expire in 2015. As of December 31, 2011, the total future minimum payments under operating leases, including rent and office equipment, were as follows (in thousands):

2012	\$ 1,065
2013	792
2014	25
2015	4
2016	—
Thereafter	—
	<u>\$ 1,886</u>

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. Rent expense, net of sublease rent income, for the years ended December 31, 2011, 2010 and 2009 was \$864,000, \$859,000 and \$653,000, respectively.

#### ***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. During 2011, the Company increased its pledged amount by \$300,000 related to an increase in its credit limit. These funds are therefore classified as restricted cash on the Company's balance sheet at December 31, 2011 and 2010, respectively.

#### ***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 with an initial term of five years. Pursuant to the terms of the Supply Agreement, Baxter received development fees from the Company upon the completion of specified development activities, which the Company expensed as these activities had no alternative future uses at the time they were incurred. The Supply Agreement also required the Company to fund specified improvements at Baxter's manufacturing facility and purchase certain equipment for use by Baxter in manufacturing OFIRMEV. Certain equipment purchased for the manufacture of OFIRMEV to which the Company retains title, has been capitalized on the Company's balance sheets as property and equipment. During the years ended December 30, 2010 and 2009, the Company reimbursed Baxter approximately \$1,813,000 and \$952,000, respectively, for the facility improvements under this agreement, which were expensed as these costs were incurred. No reimbursements for facility improvements were made under this agreement during the year ended December 31, 2011. During the year ended December 31, 2010, the Company reimbursed Baxter \$754,000 for development fees under the Supply Agreement. No development fees were paid by the Company under the Supply Agreement during the years ended December 31, 2011 and 2009.

In January 2011, the Company amended and restated the Supply Agreement (the "Amended Supply Agreement") in connection with a plan to expand the manufacturing capacity for OFIRMEV at Baxter. Similar to the original Supply Agreement, all capital equipment and facility improvements included in the plan will be



**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

funded by the Company. The Company intends to capitalize these costs, as OFIRMEV has been approved by the FDA, however the Company is not able to reasonably estimate the cost of expansion until the capacity increase development plan is completed. Further, the Company will pay Baxter a per unit purchase price based on the amount of finished OFIRMEV drug product produced, which price will be increased annually, and may be adjusted to reflect an increase or decrease, as the case may be, in the cost of material required to manufacture OFIRMEV, subject to specified limitations. The Company is obligated to purchase a minimum number of units of OFIRMEV each year or pay Baxter an amount equal to the purchase price multiplied by the shortfall in units. In addition, Baxter will be the Company's primary supplier of OFIRMEV up to a specified number of units in each year, subject to Baxter's ability to timely supply the specified volumes required by the Company. However, if Baxter fails or declines to supply a sufficient quantity of OFIRMEV in accordance with the Company's purchase orders during a specified period of time, then the Company may purchase that quantity of OFIRMEV from third party suppliers and such quantity will be deducted from the quantity of OFIRMEV that the Company otherwise would have been required to purchase from Baxter. The Company is also 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 Company recorded a charge for the fourth quarter of 2011 and it placed certain finished product inventory of OFIRMEV on indefinite hold pending the outcome of an investigation into unidentified particulate matter observed during routine product stability testing. The Company decided to temporarily suspend further production by its primary supplier until the investigation has been completed and any necessary corrective and preventative actions have been implemented. For the year ended December 30, 2011, the Company had reimbursed Baxter approximately \$262,000 for facility improvements pursuant to the Amended Supply Agreement. No reimbursements under this agreement were made during the years ended December 31, 2010 and 2009.

The initial term of the Amended Supply Agreement will terminate on November 1, 2015, and will automatically renew for successive one-year periods thereafter, unless either party provides at least two years prior written notice of termination to the other party. In addition, either party may terminate the Agreement (1) within 90 days, after written notice in the event of a material uncured breach of the Agreement by the other party or (2) immediately, upon the filing of a petition of bankruptcy by the other party. The Company may also terminate the Agreement, effective 30 days after providing written notice, in the event that Baxter does not agree to the assignment of the Agreement by the Company to a competitor of Baxter. Baxter has agreed that, for the initial term and any renewals or extensions of the Agreement, neither it nor any of its affiliates will develop or commercially produce, for itself or for any third party, any intravenous formulation of a product containing acetaminophen for distribution or sale in the United States.

If the Amended Supply Agreement with Baxter is terminated, except as a result of a material uncured breach or bankruptcy by Baxter, the Company will reimburse Baxter for all materials ordered prior to the termination of the Amended Supply Agreement that are not cancelable at no cost to Baxter. Upon termination of the agreement and subject to certain exceptions, the Company will purchase from Baxter all undelivered products manufactured or packaged under a purchase order from the Company, at the price in effect at the time the purchase order was placed. The Company is also obligated to reimburse Baxter for reasonable costs incurred in returning all Company-owned equipment and for restoring Baxter's manufacturing facility to its condition prior to the installation of OFIRMEV-related improvements, other than restoration costs for changes that Baxter reasonably agrees are usable by Baxter at the time of removal of the Company-owned equipment. 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.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

**Lawrence Laboratories**

In December 2010, the Company entered into a supplemental Supply Agreement (the “Supplemental Agreement”) with Lawrence Laboratories (“Lawrence”), an indirectly wholly-owned subsidiary of BMS, for the manufacture of commercial supplies of the finished drug product for OFIRMEV. Bristol-Myers Squibb Srl (“BMS Anagni”), an indirect subsidiary of BMS, manufactures the product on behalf of Lawrence. BMS Anagni also currently manufactures intravenous acetaminophen for sale and distribution by BMS and its affiliates in a number of countries outside of the U.S. and Canada. At the time the Supplemental Agreement was executed, the Company submitted a supplemental NDA (“sNDA”) to the FDA, seeking the approval of the BMS Anagni facility as an additional manufacturing site for OFIRMEV. The FDA approved the BMS Anagni facility as an additional manufacturing site for OFIRMEV in March 2011.

Pursuant to the terms of the Supplemental Agreement, Lawrence will receive from the Company a set price for the OFIRMEV purchased, which prices may be adjusted by Lawrence, subject to specified limitations. In addition, the Company is obligated to purchase a minimum number of units each year following regulatory approval of OFIRMEV manufactured on behalf of Lawrence, or pay Lawrence an amount equal to the per-unit purchase price less Lawrence’s average material and direct labor costs for OFIRMEV, multiplied by the amount of the shortfall.

The Supplemental Agreement has an initial term that ends upon the 36-month anniversary of the date the sNDA is approved by the FDA, unless the Supplemental Agreement is terminated sooner: (1) by mutual agreement of the parties, (2) by either party for convenience following eighteen months’ prior written notice of termination to the other party, (3) upon the termination of the Company’s license agreement for the product with BMS, or (4) upon the dissolution or termination of the Company, other than in connection with or following the assignment of the Supplemental Agreement. In addition, either party may terminate the Supplemental Agreement: (a) within 60 days after written notice in the event of a material uncured breach of the Supplemental Agreement by the other party, or (b) immediately, if the other party becomes insolvent or admits in writing its inability to pay its debts as they become due, files a petition for bankruptcy, makes an assignment for the benefit of its creditors or has a receiver or other court officer appointed for its properties or assets.

If the Supplemental Agreement is terminated by the Company for its convenience or by Lawrence due to the Company’s material breach of the agreement, the Company will reimburse Lawrence for: (1) any product ordered under a firm order and received by the Company, and (2) any inventory of materials used to manufacture OFIRMEV that are specific to OFIRMEV and that Lawrence is unable to reasonably utilize. Additionally, the Company’s minimum purchase requirement for the year in which the termination takes effect will be reduced proportionally, and the Company will not be required to fulfill the minimum purchase requirement for any subsequent contract year. If the Supplemental Agreement is terminated for any reason other than by the Company for its convenience or by Lawrence due to the Company’s material breach of the agreement, the Company will not be required to reimburse Lawrence for any inventory of materials used to manufacture OFIRMEV, and will have no obligation to purchase the minimum purchase requirement for the year in which the termination takes effect, or for any subsequent contract year.

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**NOTES TO FINANCIAL STATEMENTS—Continued**

The combined minimum purchase requirements under the Company's two supply agreements as of December 31, 2011 were as follows (in thousands):

2012	\$14,397
2013	15,440
2014	6,613
2015	3,083
2016	—
Thereafter	—
Total	<u>\$39,533</u>

The ultimate liability for these obligations may be reduced if one or more of the Company's suppliers fails or declines to supply a sufficient quantity of OFIRMEV in accordance with the Company's purchase orders.

#### **9. 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 OFIRMEV in the U.S. and Canada from BMS. BMS sublicensed these rights to the Company under a license agreement with Pharmatop. As consideration for the license, the Company paid a \$25,000,000 up-front fee and, as a result of the approval of the Company's NDA for OFIRMEV in the fourth quarter of 2010, the Company paid an additional milestone payment of \$15,000,000 in the fourth quarter of 2010. The Company may be required to make future milestone payments totaling up to \$25,000,000 upon the achievement of certain levels of net sales. 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. The amount of such royalty ranges from the mid-teens to the mid-twenties, depending on the aggregate amount of net sales, and is subject to annual minimum royalty obligations. The \$25,000,000 up-front fee was recognized as research and development expense at the time the payment was made. The \$15,000,000 milestone payment was recorded as an intangible asset on the Company's balance sheets and is being amortized over the estimated useful life of the licensed patents. Royalty liabilities are recognized at the time the product is sold or, for minimum royalty obligations that are not anticipated to be met, over the period in which the minimum liability is incurred.

In November 2010, the Company has entered into a data license agreement among Terumo Corporation ("Terumo"), the Company and SCR Pharmatop S.A. ("Pharmatop"). Under the data license agreement, the Company provided to Terumo certain data and information resulting from the Company's clinical development program for OFIRMEV for Terumo's use in obtaining regulatory approval for and commercializing the same intravenous formulation of acetaminophen in Japan. Further, the Company will provide to Terumo, without charge, up to 500 hours of technical assistance and consulting services regarding the licensed technical information, data and know-how, as reasonably necessary to assist Terumo in obtaining regulatory approval and manufacturing capacity for the product candidate. In April 2011, the Company received an upfront payment of \$5,329,000 under the terms of the data license agreement. If Terumo is successful in obtaining regulatory approval for and commercializing the product in Japan, the Company may also be entitled to an additional lump-sum payment upon the first commercial sale of the product candidate and royalty payments on any commercial sales of the product in Japan.

In accordance with multiple-element arrangement guidance, the Company determined both the data license and consulting service deliverables were separate units of accounting, each having value on a standalone basis. The Company estimated the fair value of the data license based upon similar proposals from third parties and internal costs incurred in developing the data and obtaining similar rights. The value of the consulting services

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

was based on contracts the Company had engaged with third parties for similar services. The Company allocated the value of the payment received on a relative fair value basis and will recognize the consideration allocated to the data license upon delivery and the consideration allocated to the consulting services as such services are rendered. There is no right of return or similar refund provisions in the data license agreement. During 2011, the Company transferred the data and related information to Terumo and provided a portion of the consulting hours. For the year ended December 31, 2011, the Company recognized \$5,210,000 of licensing revenue pursuant to the agreement for the data transfer and consulting hours provided. The remaining balance of \$119,000 reflects the value of the outstanding consulting hours the Company is obligated to provide under the terms of the contract through November 2012. This balance is recorded as deferred revenue on the Company's balance sheet at December 31, 2011 and will be recognized as revenue as the consulting services are rendered. Any milestones or royalties received from potential sales of the product candidate will be recognized as revenue in the period earned. No similar revenue was recognized during the years ended December 31, 2010 and 2009.

**10. Legal Matters**

In August 2011, the Company and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock Laboratories, Inc., Perrigo Company and Paddock Laboratories, LLC (collectively, "Paddock") and against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc. (collectively, "Exela"). The lawsuit follows the notices that the Company received in July 2011 from each of Paddock and Exela concerning their filings of Abbreviated New Drug Applications, or ANDAs, containing a "Paragraph IV" patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit the Company alleges that Paddock and Exela have each infringed U.S. Patent Nos. 6,028,222 (the "'222 patent"), and 6,992,218 (the "'218 patent"), by filing their respective ANDAs seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The '222 and the '218 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA until the earlier of the expiration of a 30-month period, the expiration of the '222 and '218 patents, the entry of a settlement order or consent decree stating that the '222 and '218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Paddock or Exela, or such shorter or longer period as the Court may order. Each of Paddock and Exela has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed counterclaims. A date for the bench trial in this case has been tentatively scheduled for May 2013. Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. Specifically, the FDA has granted OFIRMEV three years of regulatory exclusivity, which expires November 2, 2013. The Company intends to vigorously enforce its intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of its patents. The '222 patent expires August 5, 2017 (or February 5, 2018 if pediatric exclusivity is granted) and the '218 patent expires June 6, 2021 (or December 21, 2021 if pediatric exclusivity is granted). However, given the unpredictability inherent in litigation, the Company cannot predict the outcome of this matter or any other litigation.

**11. Stockholders' Equity**

***Public Offerings***

In November 2011, the Company issued an aggregate of 21,800,000 shares of its common stock at a purchase price of \$3.75 per share pursuant to a public offering. In November and December 2010, the Company issued an aggregate of 12,500,000 shares of its common stock at a purchase price of \$8.00 per share pursuant to a public offering. The 2011 and 2010 offerings raised proceeds, net of offering costs and underwriting discounts and commissions, of \$77,302,000 and \$93,555,000, respectively.

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

***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 and have been accounted for as permanent equity. As of December 31, 2011, all warrants related to the private placement were outstanding.

The private placement raised proceeds, net of offering costs, of \$86,243,000. 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.

***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 was amended and restated in 2010 to preserve the ability to deduct compensation associated with future performance-based awards made under the plan to certain executives. The term of the 2006 Plan was also extended under the 2010 amendment to 2020.

The 2006 Plan initially reserved 2,100,000 shares of common stock for future issuance and allowed for the initial number of reserved shares to be increased by (1) 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 (2) 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, 2011, 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 (1) 4% of the outstanding common stock on January 1 and (2) 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 through January 1, 2016. Through December 31, 2011, the board of directors approved the amount of shares authorized for future issuance under the 2006 Plan to be increased by an aggregate 5,948,695 shares under this provision.

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

As of December 31, 2011, 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, 2011:

	<u>Authorized</u>	<u>Available</u>	<u>Outstanding</u>
2004 Equity Incentive Plan	2,709,475	—	1,031,478
2006 Equity Incentive Plan	8,214,220	1,014,264	6,942,131
	<u>10,923,695</u>	<u>1,014,264</u>	<u>7,973,609</u>

The Company issues new shares of common stock upon the exercise of stock options and vesting of RSU awards. Shares that are tendered or withheld to satisfy the exercise price or tax withholding obligation pursuant to the award are returned to the pool of available shares for future grant.

**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 following table summarizes the Company's stock option activity as of December 31, 2011, and changes for the year then ended:

	<u>Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Life - Years</u>	<u>Aggregate Intrinsic Value</u>
Options outstanding at beginning of period	6,999,657	\$ 7.84		
Granted	1,844,525	\$ 8.50		
Exercised	(507,515)	\$ 3.16		
Cancelled	(367,434)	\$ 9.69		
Options outstanding at end of period	<u>7,969,233</u>	<u>\$ 8.21</u>	<u>7.03</u>	<u>\$ 1,844,000</u>
Options exercisable at end of period	<u>4,907,056</u>	<u>\$ 7.89</u>	<u>6.02</u>	<u>\$ 1,842,000</u>

The aggregate intrinsic value of options exercised during 2011, 2010 and 2009 was \$2,774,000, \$792,000 and \$700,000, respectively. During 2011, the Company received \$1,603,000 upon the exercise of stock options.

**Restricted Stock Units**

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 were not achieved. As such, the awards were forfeited and all previously recorded expense associated with these RSUs was recovered. The remaining half of

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**NOTES TO FINANCIAL STATEMENTS—Continued**

the RSUs, adjusted for cancellations from terminations, vested upon the first anniversary of the approval by the FDA of the NDA for OFIRMEV, or November 2, 2011. An additional 13,500 RSUs were granted in 2010, of which a portion had vested as of December 31, 2011.

The following table summarizes the Company's RSU activity as of December 31, 2011, and changes for the year then ended:

	Shares	Weighted-Average Grant Date Fair Value per Share	Aggregate Intrinsic Value
Restricted stock units outstanding at beginning of period	135,658	\$ 10.87	
Granted	—	—	
Vested	(124,500)	\$ 10.90	
Cancelled	(6,782)	\$ 10.79	
Restricted stock units outstanding at end of period	<u>4,376</u>	<u>\$ 10.38</u>	<u>\$ 17,000</u>

The aggregate intrinsic value of RSUs vested during 2011 and 2010 was \$716,000 and \$33,000, respectively. There was no vesting of RSUs in 2009. During 2011, a total of 27,769 vested shares were withheld from distribution in satisfaction of statutory minimum tax obligations and the Company used \$159,000 to satisfy such tax obligations.

**12. 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 and the Company operates and manages its business as principally one segment. It sells its only product, OFIRMEV, primarily to established wholesale distributors in the pharmaceutical industry, including the nation's three leading wholesale pharmaceutical distributors: Cardinal Health, Inc., AmerisourceBergen Corporation and McKesson Corporation.

Shipments to wholesalers representing approximately 10% or more of total product revenue for the periods presented were as follows (as a percentage of total gross product revenue):

	Year Ended December 31,		
	2011	2010	2009
Cardinal Health, Inc.	37%	—	—
AmerisourceBergen Corporation	33%	—	—
McKesson Corporation	23%	—	—

Related receivables from customers representing approximately 10% or more of total product revenue for each period are as follows (as a percentage of total gross trade receivables):

	Year Ended December 31,		
	2011	2010	2009
Cardinal Health, Inc.	35%	—	—
AmerisourceBergen Corporation	36%	—	—
McKesson Corporation	21%	—	—

**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

**13. 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 state 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, 2011 and 2010, and has recognized no interest and/or penalties in the Company's statement of operations for the years ended December 31, 2011, 2010 and 2009. Further, as of December 31, 2011, the Company had not recorded any unrecognized tax benefits.

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 of a cumulative change in ownership of more than 50% within a three-year period. The Company has not completed this analysis regarding the limitation and therefore has removed the (1) deferred tax assets for net operating losses of approximately \$123,436,000 and (2) research and development credits of approximately \$6,562,000 generated through 2011 from its deferred tax asset schedule. Further, the Company has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its deferred tax asset and valuation allowance accordingly. The Company expects to complete this analysis within the next 12 months and, as a result, the Company may have a change in the unrecognized tax benefits that are recorded. 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.

A valuation allowance has been established as realization of such deferred tax assets has not met the more likely than not threshold requirement. Other significant components of the Company's deferred tax assets for federal and state income taxes at December 31, 2011 and 2010 are shown below (in thousands):

	As of December 31,	
	2011	2010
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ —	\$ —
Tax credit carryforwards	—	—
Stock-based compensation	10,394	9,007
Capitalized research and development	6,360	7,115
Other, net	1,651	2,302
	<u>18,405</u>	<u>18,424</u>
Valuation allowance for deferred tax assets	(18,405)	(18,424)
<b>Net deferred tax assets</b>	<u>\$ —</u>	<u>\$ —</u>

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

	As of December 31,		
	2011	2010	2009
Federal income taxes	35.0%	35.0%	35.0%
State income taxes	4.3%	5.8%	5.8%
Research and development credits	0.9%	1.0%	2.4%
Stock-based compensation	(0.7)%	(1.7)%	(1.7)%
Change in federal valuation allowance	0.0%	(4.3)%	(5.9)%
Prior year true-up	(0.0)%	0.3%	2.3%
Removal of net operating loss and research and development tax credits	(37.8)%	(35.7)%	(37.4)%
Other, net	(1.7)%	(0.4)%	(0.5)%
	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>



**CADENCE PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS—Continued**

At December 31, 2011, the Company had federal and state net operating loss carryforwards of approximately \$306,480,000 and \$309,950,000, 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 research and development tax credit carryforwards of approximately \$4,753,000 which will begin expiring in 2024 unless previously utilized, and state research and development tax credit carryforwards of approximately \$2,785,000 which carryforward indefinitely.

Included in the net operating loss carryforwards is approximately \$975,000 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.

**14. 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 2011, 2010 and 2009, the Company elected not to make any contributions to the plan.

**15. 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, 2011 and 2010 are as follows (in thousands, except share and per share data):

	Fiscal Year 2011 Quarters				Total
	1st	2nd <sup>(4)</sup>	3rd	4th <sup>(5)</sup>	
Revenues <sup>(1)</sup>	\$ 350	\$ 6,916	\$ 3,541	\$ 5,889	\$ 16,696
Gross profit (loss) <sup>(1)</sup>	\$ 61	\$ 5,935	\$ 1,223	\$ (2,929)	\$ 4,290
Net loss	\$(24,372)	\$(19,214)	\$(21,829)	\$(27,606)	\$(93,021)
Basic and diluted net loss per share <sup>(2)(3)</sup>	\$ (0.39)	\$ (0.30)	\$ (0.34)	\$ (0.37)	\$ (1.41)

	Fiscal Year 2010 Quarters				Total
	1st	2nd <sup>(6)</sup>	3rd <sup>(6)</sup>	4th	
Revenues <sup>(1)</sup>	\$ —	\$ —	\$ —	\$ —	\$ —
Gross profit <sup>(1)</sup>	\$ —	\$ —	\$ —	\$ —	\$ —
Net loss	\$(13,919)	\$(12,219)	\$(11,712)	\$(18,793)	\$(56,643)
Basic and diluted net loss per share <sup>(2)(3)</sup>	\$ (0.28)	\$ (0.24)	\$ (0.23)	\$ (0.33)	\$ (1.09)

<sup>(1)</sup> The Company commenced commercial sales of OFIRMEV in January 2011. As such, there were no similar revenues or related gross profit during the 2010 periods.

<sup>(2)</sup> 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.

<sup>(3)</sup> In the fourth quarter of 2011 and 2010, the Company issued 21,800,000 shares and 12,500,000 shares, respectively, of common stock. As a result, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented.

**CADENCE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS—Continued**

- (4) During the second quarter of 2011, the Company recognized \$5,210 in license revenue under a data license agreement with Terumo Corporation, primarily related to the one-time transfer of data and related information.
- (5) During the fourth quarter of 2011, the Company recorded a charge of \$5,574 to write-down the value of certain inventory. Further, the Company recorded one-time employee charges of \$1,142 related to a reduction in force of 17 employees. Relatedly, \$251 of previously accrued labor-related costs for these individuals was reversed at the time of the termination.
- (6) During the second and third quarters of 2010, the Company recorded charges of \$1,186 and \$336, respectively, related to the partial cancellation of an equipment order.

**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, 2011 that has materially affected, 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 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, 2011, 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, 2011 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 internal control over financial reporting as of December 31, 2011, 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, 2011, 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, 2011 and 2010, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2011, of Cadence Pharmaceuticals, Inc. and our report dated March 13, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
March 13, 2012

**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, Information Regarding the Board of Directors and Corporate Governance, 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, 2011 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, 2011 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 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, 2011 pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference. The information required by this item regarding our equity compensation plan is included in the section above entitled "*Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities - Securities Authorized for Issuance under Equity Compensation Plans.*"

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

Information required by this item will be included under the captions *Certain Relationships and Related Transactions* and *Information Regarding the Board of Directors and Corporate Governance* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2011 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, 2011 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 66 through 95, as follows:

<a href="#">Report of Independent Registered Public Accounting Firm</a>	<u>Page</u> 66
<a href="#">Balance Sheets at December 31, 2011 and 2010</a>	67
<a href="#">Statements of Operations for the years ended December 31, 2011, 2010 and 2009</a>	68
<a href="#">Statements of Stockholders' Equity for the years ended December 31, 2011, 2010 and 2009</a>	69
<a href="#">Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009</a>	70
<a href="#">Notes to Financial Statements</a>	71

(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) List of exhibits required by Item 601 of Regulation S-K. See part (b) below.

*(b) Exhibits.*

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
3.1	Amended and Restated Certificate of Incorporation of the Company, incorporated herein by reference to Exhibit 3.1 to the Company'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 Company, incorporated herein by reference to Exhibit 3.2 to the Company'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
3.3	Amendment of Amended and Restated Bylaws of the Company, incorporated herein by reference to Exhibit 3.1 to the Company'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 Company's Common Stock Certificate, incorporated herein by reference to Exhibit 4.1 to the Company'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 Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006
4.3	Registration Rights Waiver and Amendment dated November 29, 2007, incorporated herein by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.4	Form of Warrant to Purchase Stock issued to Silicon Valley Bank on November 30, 2007, incorporated herein by reference to Exhibit 4.6 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.5	Form of Warrant to Purchase Stock issued to Oxford Finance Corporation on November 30, 2007, incorporated herein by reference to Exhibit 4.7 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007

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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
4.6	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 Exhibit 4.8 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.7	Form of Warrant to Purchase Stock issued on February 18, 2009, incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 20, 2009
4.8	Form of Warrant to Purchase Stock issued on June 18, 2010, incorporated herein by reference to Exhibit 4.10 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on June 21, 2010
4.9	Form of Warrant to Purchase Stock issued on December 22, 2011, incorporated herein by reference to Exhibit 4.10 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 27, 2011
10.1#	Form of Director and Executive Officer Indemnification Agreement, incorporated herein by reference to Exhibit 10.1 to Amendment No. 1 of the Company's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on August 30, 2006
10.2#	Amended and Restated Cadence Pharmaceuticals, Inc. Director Compensation Policy, effective September 1, 2011, incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2011 as filed with the SEC on November 4, 2011
10.3#	Form of Second Amended and Restated Employment Agreement, incorporated herein by reference to Exhibit 10.31 to the Company'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
10.4#	Employment Agreement between the Company and Scott A. Byrd, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on June 22, 2009
10.5#	2004 Equity Incentive Award Plan and forms of Option Agreements thereunder, incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-8 (File No. 333-138226) as filed with the SEC on October 26, 2006
10.6#	2010 Amendment and Restatement of the 2006 Equity Incentive Award Plan, incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-8 (File No. 333-138226) as filed with the SEC on December 23, 2010
10.7	Forms of Option and Restricted Stock Agreements under the 2006 Equity Incentive Award Plan, incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-8 (File No. 333-138226) as filed with the SEC on October 26, 2006
10.8#	Form of Deferral Restricted Stock Unit Agreement under the 2006 Equity Incentive Award Plan, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on September 2, 2009
10.9#	Form of Non-Deferral Restricted Stock Unit Agreement under the 2006 Equity Incentive Award Plan, incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on September 2, 2009
10.10#	Amended and Restated 2011 Corporate Bonus Plan, incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-33103) for the quarter ended March 31, 2011 as filed with the SEC on May 5, 2011

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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.11 <sup>±#</sup>	2012 Corporate Bonus Plan
10.12	Form of Amended and Restated Restricted Common Stock Purchase Agreement, incorporated herein by reference to Exhibit 10.6 to Amendment No. 1 of the Company's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on August 30, 2006
10.13	Form of Common Stock Purchase Agreement dated February 14, 2008, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 15, 2008
10.14	Securities Purchase Agreement, dated February 13, 2009, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 20, 2009
10.15	Lease dated May 12, 2006 by and between the Company and Prentiss/Collins Del Mar Heights LLC, incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006
10.16 <sup>±</sup>	First Amendment to Lease dated September 29, 2006 by and between the Company and Prentiss/Collins Del Mar Heights LLC
10.17 <sup>±</sup>	Second Amendment to Lease dated December 8, 2011 by and among the Company and PRII High Bluffs LLC and Collins Corporate Center Partners, LLC
10.18 <sup>†</sup>	IV APAP Agreement (U.S. and Canada) dated February 21, 2006 by and between the Company and Bristol-Myers Squibb Company, incorporated herein by reference to Exhibit 10.11 to Amendment No. 2 of the Company's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on September 25, 2006
10.19 <sup>†</sup>	License Agreement dated December 23, 2002 by and among SCR Pharmatop and Bristol-Myers Squibb Company, incorporated herein by reference to Exhibit 10.12 to Amendment No. 2 of the Company's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on September 25, 2006
10.20 <sup>†</sup>	Supply Agreement dated December 1, 2010 by and between the Company and Lawrence Laboratories, an indirect wholly-owned subsidiary of Bristol-Myers Squibb Company, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 2, 2010
10.21 <sup>†</sup>	Amended and Restated Development and Supply Agreement by and between the Company and Baxter Healthcare Corporation dated January 28, 2011, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 2, 2011
10.22 <sup>†</sup>	Amended and Restated Loan and Security Agreement dated June 18, 2010 by and among the Company and Oxford Finance Corporation, Silicon Valley Bank and GE Business Financial Services, Inc., incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on June 21, 2010
10.23	First Amendment to Amended and Restated Loan and Security Agreement dated November 22, 2010 by and among the Company and Oxford Finance Corporation, Silicon Valley Bank and GE Business Financial Services, Inc., incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on November 26, 2010



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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.24	Second Amended and Restated Loan and Security Agreement dated December 22, 2011 by and among the Company and Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 27, 2011
10.25 <sup>†</sup>	Option Agreement dated June 21, 2010 by and among the Company and Incline Therapeutics, Inc., incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended June 30, 2010 as filed with the SEC on August 6, 2010
23.1 <sup>±</sup>	Consent of Independent Registered Public Accounting Firm
31.1 <sup>±</sup>	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 <sup>±</sup>	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 <sup>±</sup>	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
101.INS <sup>±</sup>	XBRL Instance Document
101.SCH <sup>±</sup>	XBRL Taxonomy Extension Schema Document
101.CAL <sup>±</sup>	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF <sup>±</sup>	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB <sup>±</sup>	XBRL Taxonomy Extension Label Linkbase Document
101.PRE <sup>±</sup>	XBRL Taxonomy Extension Presentation Linkbase Document

<sup>±</sup> Included in this Report.

<sup>#</sup> Indicates management contract or compensatory plan.

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



## CADENCE PHARMACEUTICALS, INC.

## BONUS PLAN

Effective January 1, 2012

**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 employees 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 on 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 30<sup>th</sup> of the applicable Plan year but prior to October 1<sup>st</sup> 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 1<sup>st</sup> 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:

<u>Position Title</u>	<u>Bonus Percentage</u>
President/CEO	75%
EVP, SVP	40%
VP	30%
Executive Director, Senior Director	25%
Director	20%
Medical Science Liaison	15%
Associate Director, Senior Manager	15%
Manager	10%
Analyst/Specialist	8%
Administrative/Accounting Associate	6%

**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, in the case of executive officers, 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:

	<u>Corporate</u>	<u>Individual</u>
President/CEO	100%	
EVP/SVP	75%	25%
VP	60%	40%
Exec Dir/Sr Dir/Dir/Assoc Dir/Sr Mgr/MSL	50%	50%
Manager	40%	60%
Analyst/Specialist/Administrative	30%	70%

**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.

<u>Performance Category</u>	<u>Award Multiplier</u>
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.

<b>Example:</b>	<u>Step # 1: Potential Bonus Award Calculation</u>	
	Position:	Director
	Base salary:	\$100,000
	Target bonus percentage:	20%
	Potential base bonus:	\$20,000
<b>Step # 2:</b>	<u>Split award target amount based on weighting of Performance Factors</u>	
	Potential corporate performance bonus (50%):	\$10,000
	Potential individual performance bonus (50%):	\$10,000
<b>Step # 3:</b>	<u>Actual Cash Incentive Award Calculation</u>	
	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	<u>\$12,500</u> (\$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.*

**FIRST AMENDMENT TO LEASE**  
**(High Bluff Ridge)**

THIS FIRST AMENDMENT TO LEASE (this "**First Amendment**") is made and entered into as of September 29, 2006 by and between PRENTISS/COLLINS DEL MAR HEIGHTS LLC, a Delaware limited liability company, as tenants in common ("**Landlord**"), and CADENCE PHARMACEUTICALS, INC., a Delaware corporation ("**Tenant**").

**R E C I T A L S:**

A. Landlord and Tenant entered into that certain Office Lease dated as of May 12, 2006 (the "**Lease**"). Capitalized terms used herein without definition shall have the meanings set forth for such terms in the Lease.

B. Pursuant to, and as more particularly described in the Lease, Landlord leases to Tenant certain space in a building located at 12481-12531 High Bluff Drive, City of San Diego, County of San Diego, State of California.

B. Landlord and Tenant now desire to amend the Lease to reduce the unreserved, uncovered parking privileges provided to Tenant under the Lease, subject to the terms and conditions set forth herein.

**A G R E E M E N T:**

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Amendment.** Section 1.16 of the Lease is amended and restated in its entirety to read as follows:

"1.16 **Parking:** A total of ninety-eight (98) parking privileges at the 12481 Building, which shall be comprised of (i) a minimum of seventy-one (71) unreserved; uncovered parking privileges at no additional cost to Tenant, and (ii) a maximum of twenty-seven (27) reserved, covered parking privileges at an additional cost to Tenant of \$100 per stall per month. All such parking privileges shall be subject to the provisions set forth in **Section 6.2** of this Lease."

(a) **Miscellaneous.** This First Amendment embodies the entire understanding between Landlord and Tenant with respect to its subject matter and can be changed only by an instrument in writing signed by Landlord and Tenant. This First Amendment may be executed in counterparts, including facsimile counterparts, each of which shall be deemed an original, but all of which, together, shall constitute one and the same First Amendment. Each individual executing this First Amendment that he or she is duly authorized to execute and deliver this First Amendment. Landlord and Tenant each hereby acknowledges and reaffirms all of its obligations under the Lease, as such Lease has been amended by this First Amendment, and agrees that any reference made in any other document to the Lease shall mean the Lease as amended pursuant to this First Amendment. Except as expressly provided herein, the Lease remains, unmodified and in full force and effect. The Lease shall remain in full force and effect and binding upon the parties hereto except as otherwise addressed herein.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date and year first set forth above.

**LANDLORD:**

**PRENTISS/COLLINS DEL MAR HEIGHTS LLC,**  
a Delaware limited liability company,

By: The Prudential Insurance Company of America,  
a New Jersey Corporation  
Its sole member

By: /s/ Darin Bright  
Darin Bright, Vice President

**TENANT:**

**CADENCE PHARMACEUTICALS, INC.,**  
a Delaware corporation

By: /s/ William R. LaRue  
Name: William R. LaRue  
Title: SVP-CFO



**SECOND AMENDMENT TO LEASE**  
**(High Bluff Ridge)**

THIS SECOND AMENDMENT TO LEASE (this "**Amendment**") is made and entered into as of December 8, 2011 the "**Effective Date**"), by and between PRII HIGH BLUFFS LLC, a Delaware limited liability company, and COLLINS CORPORATE CENTER PARTNERS, LLC, a Delaware limited liability company, as tenants in common ("**Landlord**"), and CADENCE PHARMACEUTICALS, INC., a Delaware corporation ("**Tenant**").

**R E C I T A L S:**

A. Prentiss/Collins Del Mar Heights LLC, a California limited liability company ("**Original Landlord**") and Tenant entered into that certain Office Lease dated as of May 12, 2006, as amended by that certain Amendment to Lease dated September 29, 2006 (as amended, the "**Lease**"). Landlord has succeeded to the interest of Original Landlord under the Lease. Pursuant to, and as more particularly described in, the Lease, Landlord leases to Tenant certain space in a building located at 12481 High Bluff Drive, San Diego, California (the "**Building**"), which space consists of approximately 23,494 rentable (22,405 usable) square feet, located on the second (2<sup>nd</sup>) floor of the Building and known as Suite 200 (the "**Premises**"), all as more particularly described in the Lease.

B. Landlord and Tenant now desire to amend the Lease to, among other things, reduce the Premises subject to the Lease and extend the Term.

**A G R E E M E N T:**

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Defined Terms.** Capitalized terms used herein without definition shall have the meanings set forth for such terms in the Lease.
2. **Extension of Term.** The Term is hereby extended for a fifteen (15) month period commencing on October 1, 2012 and expiring on December 31, 2013.
3. **Partial Termination of Lease.** On September 30, 2012 (the "**Partial Termination Date**"), the Lease, as amended hereby, shall terminate with respect to approximately 6,890 rentable square feet of the Premises (the "**Give Back Space**"), which Give Back Space is more particularly described as the "Give Back Space" on **Exhibit A** attached hereto. On the Partial Termination Date, (a) Tenant shall surrender the Give Back Space to Landlord in the condition required under the terms of the Lease, as amended hereby (i.e., upon expiration or termination of the Lease), (b) the Lease, as amended hereby, shall terminate with respect to the Give Back Space and (c) the parties hereto shall have no further rights or obligations with respect to the Give Back Space other than those rights and obligations which survive the expiration or termination of the Lease, as amended hereby. From and after the Partial Termination Date all references in the Lease, as amended hereby, to the "Premises" shall be deemed to be references to approximately 16,604, rentable square feet of the Premises (the "**Renewal Space**"), which Renewal Space is more particularly described as the "Renewal Space" on **Exhibit A** attached hereto.

4. **Monthly Basic Rent.** Notwithstanding anything to the contrary in the Lease, commencing April 1, 2012, Monthly Basic Rent is as follows:

<u>Period</u>	<u>Monthly Basic Rent</u>	<u>Approximate Monthly Basic Rent Per Rentable Square Foot</u>
04/01/12 – 09/30/12	\$90,451.90	\$3.85
10/01/12 – 12/31/13	\$63,925.40	\$3.85

5. **Parking.** With respect to the period from and after the Partial Termination Date, Section 1.16 of the Lease is amended and restated in its entirety to read as follows:

“1.16 **Parking:** A total of sixty-six (66) parking privileges at the 12481 Building, which shall be comprised of (i) a minimum of forty-eight (48) unreserved, uncovered parking privileges at no additional cost to the Tenant, and (ii) a maximum of eighteen (18) reserved, covered parking privileges at an additional cost to Tenant of \$100 per stall per month. All such parking privileges shall be subject to the provisions set forth in Section 6.2 of this Lease.”

6. **Tenant’s Percentage.** With respect to the period from and after the Partial Termination Date, the defined term, “Tenant’s Percentage” shall mean 10.51%.

7. **No Extension Option.** Section 37 of the Lease is deleted in its entirety. Tenant has no right to extend the Term.

8. **Condition of Premises.** Tenant hereby agrees to accept the Premises in their “as-is” condition, and Tenant hereby acknowledges that Landlord shall not be obligated to provide or pay for any work or services related to the maintenance, repair or improvement of the Premises. Tenant also acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty regarding the condition of all or any portion of the Premises.

9. **Anti-Terrorism Representations.**

9.1 Tenant is not, and shall not during the Term become, a person or entity with whom Landlord is restricted from doing business under the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, H. R. 3162, Public Law 107-56 (commonly known as the “USA Patriot Act”) and Executive Order Number 13224 on Terrorism Financing, effective September 24, 2001 and regulations promulgated pursuant thereto (collectively, “**Anti-Terrorism Laws**”), including without limitation persons and entities named on the Office of Foreign Asset Control Specially Designated Nationals and Blocked Persons List (collectively, “**Prohibited Persons**”).

9.2 To the best of its knowledge, Tenant represents and warrants to Landlord that it is not currently engaged in any transactions or dealings, or otherwise associated with, any

Prohibited Persons in connection with the use or occupancy of the Premises or the Project. Tenant covenants that it will not, during the Term knowingly engage in any transactions or dealings, or be otherwise associated with, any Prohibited Persons in connection with the use or occupancy of the Premises or the Project.

9.3 Tenant acknowledges and agrees that as a condition to the effectiveness of an assignment of, or sublease under, the Lease, as amended hereby, and to the requirement or effectiveness of any consent to assignment or sublease by Landlord, Tenant shall cause the assignee or sublessee to make, on behalf of such assignee or sublessee for the benefit of Landlord, the representations set forth in Section 36 of the Lease and this Section 9, and it shall be reasonable for Landlord to refuse to consent to an assignment of, or sublease under, the Lease, as amended by this Amendment, in the absence of such representations by any such assignee or sublessee.

#### 10. Miscellaneous.

(a) Entire Agreement. This Amendment embodies the entire understanding between Landlord and Tenant with respect to its subject matter and can be changed only by an instrument in writing signed by Landlord and Tenant.

(b) Counterparts. This Amendment may be executed in counterparts, including facsimile counterparts, each of which shall be deemed an original, but all of which, together, shall constitute one and the same Amendment.

(c) Brokers. Tenant represents and warrants that it has been represented by Studley, Inc. ("**Tenant's Broker**") in connection with this Amendment. If the transactions contemplated by this Amendment are consummated, subject to the terms of Landlord's separate agreement with Tenant's Broker, Landlord shall pay Tenant's Broker a commission. Except as described herein, Landlord shall have no further or separate obligation for payment of commissions or fees to any other real estate broker, finder or intermediary, including, without limitation, any commissions or fees in connection with the ROFO or the Option. Tenant represents and warrants to the other, that no other broker, agent or finder (a) negotiated or was instrumental in negotiating or consummating this Amendment on its behalf, and (b) is or might be entitled to a commission or compensation in connection with this Amendment as a result of its actions or inactions. Tenant shall indemnify, protect, defend (by counsel reasonably approved in writing by Landlord) and hold Landlord harmless from and against any and all claims, judgments, suits, causes of action, damages, losses, liabilities and expenses (including attorneys' fees and court costs) resulting from any breach by Tenant of the foregoing representation, including, without limitation, any claims that may be asserted against Landlord by any broker, agent or finder undisclosed by Tenant herein. The Section 10 shall survive the expiration or earlier termination of the Lease, as amended by this Amendment.

(d) Defaults. Tenant hereby represents and warrants to Landlord that each of Landlord and Tenant is in full compliance with all terms, covenants and conditions of the Lease and that there are no breaches or defaults under the Lease by Landlord or Tenant, and that Tenant knows of no events or circumstances which, given the passage of time, would constitute a breach or default under the Lease by either Landlord or Tenant.

(e) Authority. Each individual executing this Amendment for the Tenant represents that he or she is duly authorized to execute and deliver this Amendment for the Tenant and the Amendment is binding upon the Tenant, its successors and assigns in accordance with its terms.

(f) Reaffirmation of Obligations. Landlord and Tenant each hereby acknowledges and reaffirms all of its obligations under the Lease, as such Lease has been amended by this Amendment, and agrees that any reference made in any other document to the Lease shall mean the Lease as amended pursuant to this Amendment. Except as expressly provided herein, the Lease remains unmodified and in full force and effect. The Lease shall remain in full force and effect and binding upon the parties hereto except as otherwise addressed herein. Any breach of this Amendment, including any exhibit hereto, shall constitute a breach and default under the Lease.

(g) Miscellaneous. Time is of the essence in this Amendment and the Lease and each and all of their respective provisions. The agreements, conditions and provisions herein contained shall apply to and bind the heirs, executors, administrators, successors and assigns of the parties hereto. If any provisions of this Amendment or the Lease shall be determined to be illegal or unenforceable, such determination shall not affect any other provision of the Lease or this Amendment and all such other provisions shall remain in full force and effect. If there is any inconsistency between the provisions of this Amendment and the other provisions of the Lease, the provisions of this Amendment shall control with respect to the subject matter of this Amendment. This Amendment constitutes a part of the Lease.

**LANDLORD:**

PRII HIGH BLUFFS LLC, a Delaware limited liability company,  
as Owner Agent

By: The Prudential Insurance Company of America, an  
insurance company organized under the laws of the State  
of New Jersey, acting solely on behalf of, and for the  
benefit of, and with its liability limited to the assets of, its  
insurance company separate account PRISA II, its Sole  
Member

By: /s/ Justin C. Chapman  
Name: Justin C. Chapman  
Title: Vice President

**TENANT:**

CADENCE PHARMACEUTICALS, INC., a Delaware corporation

By: /s/ William R. LaRue  
Name: William R. LaRue  
Title: SVP, Chief Financial Officer

By: /s/ Theodore R. Schroeder  
Name: Theodore R. Schroeder  
Title: President and Chief Executive Officer

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-171396, 333-163941 and 333-138226) and Form S-3 (Nos. 333-173295, 333-170538, 333-161756, 333-158126 and 333-147721) of Cadence Pharmaceuticals, Inc. and in the related Prospectuses of our reports dated March 13, 2012, with respect to the financial statements, 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, 2011.

/s/ Ernst & Young LLP

San Diego, California  
March 13, 2012

## 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 its 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

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

Date: March 13, 2012

## 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 its 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

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

Date: March 13, 2012



**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, 2011, 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 13, 2012.

/s/ THEODORE R. SCHROEDER

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

/s/ WILLIAM R. LARUE

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**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.