

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, 2013

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 28, 2013, the last business day of the Registrant's second fiscal quarter, reported on the NASDAQ Global Market, was approximately \$423,000,000. 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 21, 2014, there were 89,183,960 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 2014 Annual Meeting of Stockholders, which is scheduled to be held on June 11, 2014. 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, 2013.

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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, 2013

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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 products we may acquire in the future. We intend to build a leading franchise in the hospital setting, continuing to focus on differentiated products with significant unmet commercial potential that are complementary to OFIRMEV and enable us to effectively leverage our commercial infrastructure.

On February 10, 2014, we entered into an agreement and plan of merger, or the Merger Agreement, with Mallinckrodt plc, or Mallinckrodt, and Madison Merger Sub, Inc., a wholly owned indirect subsidiary of Mallinckrodt, or Merger Sub, pursuant to which, and on the terms and subject to the conditions in the Merger Agreement, among other things, Merger Sub commenced a tender offer on February 19, 2014, to acquire all of the outstanding shares of our common stock at a purchase price of \$14.00 per share in cash, without interest, or the Offer Price. Following the completion of the tender offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into us, with our company surviving as an indirect wholly owned subsidiary of Mallinckrodt, pursuant to the procedure provided for under Section 251(h) of the Delaware General Corporation Law without any stockholder approvals. The Merger Agreement includes a remedy of specific performance and is not subject to a financing condition.

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

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*®, *EXPAREL*®, *IONSYS*™, *Percocet*®, *Perfalgan*®, *Toradol*®, *Tylenol*®, *Tylenol Codeine #3 McNeil*®, *Ultram*®, and *Vicodin*®.

Agreement and Plan of Merger with Mallinckrodt plc

On February 10, 2014, we entered into the Merger Agreement with Mallinckrodt and Merger Sub pursuant to which, and on the terms and subject to the conditions in the Merger Agreement, among other things, Merger Sub commenced a tender offer on February 19, 2014, to acquire all of the outstanding shares of our common

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stock at a purchase price of \$14.00 per share in cash, without interest. The Merger Agreement includes a remedy of specific performance and is not subject to a financing condition.

The obligation of Merger Sub to purchase the shares of our common stock validly tendered pursuant to the tender offer is subject to the satisfaction or waiver of a number of conditions set forth in the Merger Agreement, including (1) that there must have been validly tendered and not validly withdrawn a number of shares of our common stock that, when added to the shares then owned by Mallinckrodt and its subsidiaries, represents one more than 50% of the total number of shares of our common stock outstanding at the time of the expiration of the tender offer, (2) the expiration or termination of applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act, (3) the accuracy of the representations and warranties and compliance with covenants contained in the Merger Agreement, (4) the absence of any law, order, injunction or decree by any government, court or governmental entity that would make illegal or otherwise prohibit the tender offer or the merger, (5) there not having been a material adverse effect with respect to our company, (6) the delivery of certain audited and unaudited financial statements, and (7) other customary conditions.

The Merger Agreement contains certain termination rights in favor of each our company and Mallinckrodt, including under certain circumstances, the requirement for us to pay to Mallinckrodt a termination fee of approximately \$20.2 million, or approximately 1.5% of the Offer Price. We also agreed (1) to cease any existing, and agreed not to solicit or initiate any additional, discussions with third parties regarding other proposals to acquire us and (2) to certain restrictions on our ability to respond to such proposals, subject to fulfillment of certain fiduciary requirements of our board of directors.

Following the completion of the tender offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into us, with our company surviving as an indirect wholly owned subsidiary of Mallinckrodt, pursuant to the procedure provided for under Section 251(h) of the Delaware General Corporation Law without any stockholder approvals. At the effective time of this merger, or the Effective Time, by virtue of the merger and without any action on the part of the holders of any shares of our common stock, each outstanding share of our common stock, other than any shares owned by Mallinckrodt, Merger Sub or any wholly owned subsidiary of Mallinckrodt or held in our treasury, or any stockholders who are entitled to and who properly exercise appraisal rights under Delaware law, will be canceled and converted into the right to receive an amount in cash equal to the Offer Price. In addition, (1) effective as of immediately prior to the Effective Time, each of our outstanding stock options will fully vest and automatically be canceled and terminated as of the Effective Time and the holder thereof will be entitled to receive an amount in cash, without interest and less the amount of any tax withholding, equal to the product of (a) the number of shares of our common stock underlying such option multiplied by (b) the excess, if any, of the Offer Price over the exercise price per share of such option, (2) effective as of immediately prior to the Effective Time, each of our outstanding restricted stock units, other than any restricted stock unit issued or awarded on or after January 1, 2014, or the Specified Restricted Stock Units, will fully vest and the restrictions thereon will lapse, and each such restricted stock unit will be canceled and converted into the right to receive an amount in cash, without interest and less the amount of any tax withholding, equal to the product of (a) the Offer Price multiplied by (b) the number of shares of our common stock underlying such restricted stock unit, and (3) at the Effective Time, each outstanding Specified Restricted Stock Unit will be canceled and converted into an award, or a Converted Award, representing the right to receive an amount in cash equal to the product of (a) the Offer Price multiplied by (b) the number of shares of our common stock underlying such Specified Restricted Stock Unit. Each Converted Award shall continue to vest and be settled in cash in accordance with the terms of the applicable Specified Restricted Stock Unit award agreement, subject to accelerated vesting under certain circumstances, including in the event of the holder's death or disability or an involuntary termination of employment that would otherwise qualify the holder to severance under any employment or severance plan or agreement to which the holder is a party or in which the holder is eligible to participate as of the date of grant. The foregoing treatment of the Specified Restricted Stock Unit Awards will supersede any more favorable vesting provisions in our equity plan or any employment or severance plan or agreement to which the holder is a party or in which the holder is eligible to participate (including employment agreements with our executive officers).

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The Merger Agreement contains customary representations, warranties and covenants, including covenants obligating us to continue to conduct our business in the ordinary course and to cooperate in seeking regulatory approvals.

Our board of directors has unanimously (1) determined that the Merger Agreement and the transactions contemplated by the Merger Agreement are advisable and fair to, and in the best interests of, our stockholders, (2) approved and declared advisable the Merger Agreement and the transactions contemplated by the Merger Agreement and (3) resolved to recommend acceptance of the tender offer by our stockholders. The board of directors of Mallinckrodt has also unanimously approved the transaction. We expect to complete the Merger in mid to late March 2014, subject to the satisfaction of the closing conditions.

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 \$54 billion or 13% of U.S. pharmaceutical sales in 2013, according to Symphony Health 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 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.

Intravenous Acetaminophen and U.S. Market Opportunity

Prior to our 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 Symphony Health Solutions, approximately 256 million vials of injectable analgesics were sold in the U.S. in 2013. 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 2013. The list price, or wholesale acquisition cost, of OFIRMEV as of January 3, 2014, was

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\$14.75 per vial. We have signed agreements with all of the major group purchasing organizations 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 are driving 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 (acetaminophen) injection 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.

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 have pain or fever warranting an intravenous formulation, were unable to take medications by other routes, required faster onset of pain relief or fever reduction, or for whom it was otherwise more convenient to receive an injectable analgesic.

Since 2002, our licensor, BMS, has marketed 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 or more potent forms of analgesia, when other administration routes are 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 function and opioid-related increased pyloric tone. As a result, published clinical studies

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have shown that dosing with IV acetaminophen provides higher plasma and cerebrospinal fluid 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 hospital 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.

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, and reduction of fever. Caldolor is not approved for use in children under 17 years of age, 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. NSAIDs are often avoided in surgical patients because they may be associated with renal toxicity, particularly in the elderly and 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 has been found to be associated with postoperative use of certain NSAIDs.

Multimodal 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 Perioperative Setting from the American Society of Anesthesiologists, or ASA, recommend that multimodal 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.

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In August 2012, The Joint Commission, an independent, not-for-profit organization that accredits and certifies more than 20,000 health care organizations and programs in the U.S., issued Sentinel Event Alert No. 49, on the safe use of opioids in hospitals. This publication advised hospitals to take specific pharmacologic and non-pharmacologic measures to reduce the incidence of serious complications that are often associated with opioid use. Specifically, this publication endorsed a multimodal approach to pain management, and recommended the use of non-narcotic analgesics, such as acetaminophen, NSAIDs, antidepressants, anticonvulsants and muscle relaxants, to reduce opioid use, particularly in patients at higher risk for over sedation and respiratory depression.

The concept of using acetaminophen for multimodal 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 multimodal approach to the perioperative setting when patients are unable to take oral medications.

Fever Reduction

Fever is an increase in internal body temperature above its average normal value due to an increased temperature regulatory set-point. 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 rates ranging from 14% to 91% of post-operative patients. Aside from the body's reaction to surgical trauma, 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 treating fever or pain in children under 17 years of age. 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 infeasible 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

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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 is highly variable, resulting in the potential for subtherapeutic dosing. 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. 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 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 1 g delivered Q6h for 24 hours 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 over 6 hours, $P < 0.01$; –33% over 24 hours, $P < 0.01$). Median time to first rescue medication was significantly longer with OFIRMEV 1 g compared

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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 ($P=0.0004$).

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 hours. 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 began enrolling patients in the third quarter of 2012 in 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 in the U.S.

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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; 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.

In addition, Exparel, a long-acting, controlled release, local anesthetic agent formulation of bupivacaine, was approved by the FDA in October 2011 as a single intraoperative injection given at the close of surgery. Exparel's manufacturer, Pacira Pharmaceuticals, Inc., has indicated that it is exploring additional indications for this product, which include regional anesthetic techniques.

Product Candidates

Competitors may seek to develop alternative formulations of intravenous acetaminophen for our targeted indications that do not directly infringe on our 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., Cara Therapeutics, Inc., Durect Corporation, Hospira, Inc., NeurogesX, Inc., Pacira Pharmaceuticals, Inc., Paion AG, QRx Pharma Limited, Relmada Therapeutics, Inc., Teva Pharmaceutical Industries Ltd., and The Medicines Company.

Generic IV Acetaminophen

In connection with a settlement and license agreements entered into in November 2012, Perrigo Company, or Perrigo, has been granted the exclusive right of first refusal to negotiate an agreement with us to market an authorized generic version of OFIRMEV in the U.S., in the event that we elect to launch an authorized generic version of the product. The license agreement also provides that, if we enter into an agreement for Perrigo to

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market an authorized generic version of OFIRMEV, during the license period, Perrigo would purchase the product exclusively from us. We would receive product costs plus an administrative fee, as well as a royalty payment based on the net profits achieved by Perrigo from the sale of the authorized generic product. Additionally, we have granted Perrigo the non-exclusive right to market a generic intravenous acetaminophen product in the U.S. under Perrigo's Abbreviated New Drug Application, or ANDA, after December 6, 2020, or earlier under certain circumstances. The Federal Trade Commission, or FTC, or the Department of Justice, or DOJ, could seek to challenge our settlement with Perrigo, or a competitor, customer or other third-party could initiate a private action under antitrust or other laws challenging our settlement with Perrigo. Additional information about the intellectual property for OFIRMEV, including the Perrigo settlement agreement and ongoing intellectual property litigation, is set forth below under the heading "Business – Intellectual Property – OFIRMEV and Pending Litigation."

In connection with a settlement agreement and a binding term sheet for a license agreement entered into in January 2014 with Sandoz, Inc., Sandoz AG, Neogen International N.V., APC Pharmaceuticals, LLC and DIACO, S.p.A., collectively the Sandoz Parties, the Sandoz Parties have the right to be granted an exclusive right of first refusal to negotiate an agreement with us to market an authorized generic version of OFIRMEV in the U.S., on substantially the same terms as those previously granted to Perrigo, in the event that we elect to launch an authorized generic version of OFIRMEV in the U.S. and Perrigo elects not to exercise its right of first refusal to become the distributor of the authorized generic version of the product. Additionally, under the terms of the license, we granted to the holder of the Sandoz ANDA and its affiliates the non-exclusive right to market a generic intravenous acetaminophen product in the United States under the Sandoz ANDA beginning December 6, 2020, or earlier under certain circumstances. The FTC or DOJ could seek to challenge our settlement with the Sandoz Parties, or a competitor, customer or other third-party could initiate a private action under antitrust or other laws challenging our settlement with the Sandoz Parties. Additional information about the intellectual property for OFIRMEV, including the Sandoz Parties settlement agreement and ongoing intellectual property litigation, is set forth below under the heading "Business – Intellectual Property – OFIRMEV and Pending Litigation."

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.

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 16 years of pharmaceutical industry experience, and an average of more than nine 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

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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.

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.

Amended and Restated Supply Agreement with Lawrence Laboratories, Inc.

In February 2013, we entered into an amended and restated supply agreement with Lawrence Laboratories, an operating division of Swords Laboratories, and a member of the BMS group of companies, which amended and restated our original agreement from December 2010, for the manufacture of commercial supplies of the finished drug product for OFIRMEV packaged in vials, for sale and distribution by us in the United States and Canada. Bristol-Myers Squibb Srl, or BMS Anagni, an indirect subsidiary of BMS located in Anagni, Italy, manufactures the product on behalf of Lawrence Laboratories. BMS Anagni is currently our sole supplier of OFIRMEV.

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Pursuant to the terms of the this Agreement, we pay Lawrence Laboratories a set price for each unit of product purchased, based upon the aggregate quantity of product that we have specified that we intend to order during a calendar year, and whether Lawrence Laboratories has implemented certain agreed-upon manufacturing capacity increase improvements. We are obligated to purchase a minimum number of units each year, or pay Lawrence Laboratories an amount equal to the shortfall between the minimum purchase requirement and the number of units of product actually ordered during such year, multiplied by a pre-set amount that also varies depending upon whether Lawrence Laboratories has implemented certain agreed-upon manufacturing capacity increase improvements. We are obligated to purchase at least 75% of our annual product requirements from Lawrence Laboratories each contract year. The agreement also requires us to pay Lawrence Laboratories for additional services requested by us at a specified hourly rate and for any validation batches that we may require, not to exceed a specified rate. All amounts payable under the agreement will be paid in U.S. dollars.

The term of this agreement extends through December 31, 2018, unless extended by the mutual agreement of us and Lawrence Laboratories, unless the agreement is terminated sooner: (1) by the mutual agreement of the parties, (2) by either party for convenience following 24 months' prior written notice of termination to the other party, (3) upon the termination of our license agreement for the product with BMS, or (4) upon our dissolution or termination, other than in connection with or following the assignment of this agreement. In addition, either party may terminate the agreement: (a) within 60 days, after written notice in the event of a material uncured breach of the 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 agreement is terminated by us for our convenience or by Lawrence Laboratories due to our material breach of the agreement, we will reimburse Lawrence Laboratories for: (1) any product ordered under a firm order and received by us, and (2) any inventory of materials used to manufacture the product that are specific to the product and that Lawrence Laboratories is unable to reasonably utilize. Additionally, our minimum purchase requirement for the year in which the termination takes effect will be reduced proportionally, and we will not be required to fulfill the minimum purchase requirement for any subsequent contract year. If the agreement is terminated for any reason other than by us for our convenience or by Lawrence Laboratories due to our material breach of the agreement, we will not be required to reimburse Lawrence Laboratories for any inventory of materials used to manufacture the product, and we 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.

Manufacturing and Supply Agreement with Laboratorios Grifols, S.A.

In March 2013, we entered into an agreement with Laboratorios Grifols, S.A., or Grifols, a division of Grifols, S.A., a global healthcare company headquartered in Barcelona, Spain, for the development, manufacture and supply of commercial quantities of OFIRMEV in flexible IV bags. Grifols has supplied IV acetaminophen in flexible plastic bags to BMS for distribution in certain markets outside of the U.S. and Canada since 2010. We submitted a supplemental NDA to the FDA in December 2013 seeking approval of the product to be manufactured by Grifols.

Pursuant to the terms of the agreement, we will pay Grifols a set price for the OFIRMEV we purchase, which price may be adjusted annually by Grifols, subject to specified limitations. In addition, we will be obligated to pay Grifols a reservation fee, in lieu of any minimum purchase commitment, calculated by multiplying the shortfall between the annual production capacity we have reserved with Grifols and the amount of product actually ordered during that year by a fixed amount. Pending review and subsequent approval of the submission by the FDA, the agreement will terminate on the sixth anniversary of the approval by the FDA of the product manufactured by Grifols, unless it is terminated sooner by us upon the termination of our license agreement for the product with BMS, or after 60 days written notice following the discontinuation of the distribution of the product by us. In addition, either party may terminate the agreement after 60 days written notice in the event of a material uncured breach of the agreement by the other party (or 30 days in the case of a payment default), or immediately upon an insolvency event.

Settlement and Termination 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. In February 2012, we temporarily suspended production of OFIRMEV by Baxter and that suspension has remained in effect through March 2013 pending an investigation into unidentified particulate matter observed during routine product stability testing and pursuant to two recalls of the product during 2012. In March 2013, we and Baxter mutually agreed to terminate the amended and restated development and supply agreement. Under the termination agreement, we were required to remove our manufacturing equipment from Baxter's facility within 180 days, and pay Baxter for anticipated costs or expenses related to such removal, but we were not required to restore Baxter's manufacturing facility to its condition prior to the installation of OFIRMEV-related improvements. In connection with the product, we were not required to reimburse Baxter for any remaining materials purchased by Baxter in connection with its manufacture of OFIRMEV. The termination agreement also contains customary mutual releases.

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 Canadian patents 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 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

'222 and '218 Patent Litigation: Exela Pharma Sciences, LLC and Paddock Laboratories, Inc. (Perrigo Company)

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 Perrigo, and against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc., collectively referred to herein as Exela. The lawsuit followed the notices that we received in July 2011 from each of Perrigo and Exela concerning their filings of ANDAs containing a "Paragraph IV" patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit, we alleged that Perrigo and Exela 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 Perrigo 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 Perrigo or Exela, or such shorter or longer period as the Court may

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order. Each of Perrigo and Exela filed an answer in the case that asserted, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims.

We settled with Perrigo and the case against Perrigo was dismissed on November 30, 2012. In connection with the settlement and license agreements entered into in November 2012, Perrigo was granted the exclusive right of first refusal to negotiate an agreement with us to market an authorized generic version of OFIRMEV in the U.S. in the event that we elect to launch an authorized generic version of the product. The license agreement also provides that, if we enter into an agreement for Perrigo to market an authorized generic version of OFIRMEV during the license period, Perrigo would purchase the product exclusively from us. We would receive product costs plus an administrative fee, as well as a royalty payment based on the net profits achieved by Perrigo from the sale of the authorized generic product. Additionally, we granted Perrigo the non-exclusive right to market a generic IV acetaminophen product in the U.S. under Perrigo's ANDA after December 6, 2020, or earlier under certain circumstances. The Federal Trade Commission, or FTC, or the Department of Justice, or DOJ, could seek to challenge our settlement with Perrigo, or a competitor, customer or other third-party could initiate a private action under antitrust or other laws challenging our settlement with Perrigo.

A bench trial for the lawsuit with Exela was held in May 2013, with one additional trial date held in early July 2013. In November 2013, the court ruled in favor of us and found that Exela's ANDA for a generic version of OFIRMEV infringed the '222 and '218 patents. An appeal of the decision in favor of us was filed by Exela on December 20, 2013. It is not possible to predict the outcome of this appeal, and an adverse outcome could result in the launch of one or more generic versions of OFIRMEV before the expiration of the last of the listed patents in June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted), which could adversely affect our ability to successfully maximize the value of OFIRMEV, and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

'222 and '218 Patent Litigation: Fresenius Kabi USA, LLC, Sandoz, Inc. and Wockhardt USA LLC

In January 2013, we filed suit in the United States District Court for the Southern District of California against Fresenius Kabi USA, LLC, or Fresenius, following receipt of a December 2012 notice from Fresenius concerning its submission of a New Drug Application, or NDA, containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In February 2013, we filed suit in the United States District Court for the Southern District of California against Sandoz, Inc., or Sandoz, following receipt of a December 2012 notice from Sandoz concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In October 2013, we filed a motion to amend our complaint against Sandoz to join Sandoz AG, Neogen International N.V., APC Pharmaceuticals, LLC, and DIACO S.p.A. (together with Sandoz, the Sandoz Parties) to the lawsuit against Sandoz due to the involvement of each of these companies with the preparation of the Sandoz ANDA and related matters.

In the lawsuits against Fresenius and the Sandoz Parties, which were coordinated for purposes of discovery and other pretrial proceedings in the Southern District of California, we alleged that Fresenius and the Sandoz Parties each infringed the '222 patent and the '218 patent by filing an NDA, in the case of Fresenius, or an ANDA, in the case of the Sandoz Parties, seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Both Fresenius and the Sandoz Parties filed answers in the Southern District of California asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims. Both the Fresenius and Sandoz lawsuits were filed within 45 days of receipt of the respective notice letters, thereby triggering a stay of FDA approval of the Fresenius NDA and the Sandoz 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 Fresenius and/or the Sandoz Parties, or such shorter or longer period as the court may order.

In January 2014, we entered into a settlement agreement and a binding term sheet for a license agreement with the Sandoz Parties. The settlement agreement includes a stipulation by the parties requesting dismissal with

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prejudice of the lawsuit filed by us relating to the ANDA filed by Sandoz. Under the terms of the license, we granted to the holder of the Sandoz ANDA and its affiliates the non-exclusive right to market a generic intravenous acetaminophen product in the United States under the Sandoz ANDA beginning December 6, 2020, or earlier under certain circumstances. We also agreed that in the event that we determine to launch an authorized generic version of OFIRMEV (i.e., a generic version marketed under our NDA) in the U.S. and Perrigo elects not to exercise its right of first refusal to become the distributor of the authorized generic version of the product, we will grant a similar right of first refusal to the holder of the Sandoz ANDA on substantially the same terms as those previously granted to Perrigo. In addition, the license agreement will contain provisions regarding indemnification, confidentiality and other customary provisions for agreements of these kinds. The settlement documents are subject to submission to the Federal Trade Commission and the U.S. Department of Justice. Litigation remains ongoing against Fresenius, and the bench trial for such lawsuit is tentatively scheduled to commence on July 14, 2014.

In December 2013, we received a notice from Wockhardt USA LLC, or Wockhardt, stating that Wockhardt filed an ANDA containing a Paragraph IV patent certification with the FDA for a generic version OFIRMEV. This notice stated that the Paragraph IV patent certification was made with respect to both the '222 patent and the '218 patent. We filed suit against Wockhardt Limited, Wockhardt BIO AG and Wockhardt on January 22, 2014 in the U.S. District Court of Delaware, and on January 23, 2014, in the U.S. District Court of New Jersey.

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 6, 2021 if pediatric exclusivity is granted). However, given the unpredictability inherent in litigation, we cannot predict the outcome of these matters or any other litigation. Regardless of how these matters are ultimately resolved, these matters may be costly, time-consuming and distracting to our management, which could have a material adverse effect on our business.

'222 and '218 Patents: Ex Parte Reexamination

In September 2012, an unidentified third party (subsequently identified as Exela) filed with the United States Patent and Trademark Office, or USPTO, a Request for Ex Parte Reexamination of the '222 patent. In December 2012, we received notice that the USPTO had granted the Request for Reexamination. The reexamination process is provided for by law and requires the USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO. In February 2013, we and Pharmatop filed with the USPTO a patent owner's statement commenting on the reexamination request, and in April 2013, Exela filed comments in response to the patent owner's statement. In a non-final, initial office action issued by the USPTO on August 14, 2013, the USPTO rejected certain claims of the '222 patent. A response to the first office action was filed in November 2013.

In addition, in January 2014, an unidentified third party filed with the USPTO a Request for Ex Parte Reexamination of the '218 patent. All of the claims of the '222 and '218 patents remain valid and in force during the reexamination proceedings. Because we and Pharmatop believe that the scope and validity of the patent claims in these patents are appropriate and that the USPTO's prior issuances of the patents were correct, we, in conjunction with Pharmatop, will vigorously defend these patents. We cannot predict whether we and Pharmatop ultimately will succeed in maintaining the scope and validity of the claims of these patents during reexamination. If any of the patent claims in these patents ultimately are narrowed during prosecution before the USPTO, the extent of the patent coverage afforded to OFIRMEV could be impaired, which could potentially harm our business and operating results.

'218 Patent Litigation: Exela Pharma Sciences, LLC

In April 2012, Exela filed suit against David J. Kappos and the USPTO in the United States District Court for the Eastern District of Virginia for declaratory judgment seeking a reversal of the USPTO's decision not to

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act on a petition by Exela to vacate the USPTO's April 2003 order reviving the international application for the '218 patent. The lawsuit followed the USPTO's rejection of Exela's petition to the USPTO filed in November 2011, which sought to vacate the April 23, 2003 order granting Pharmatop's petition to revive the '218 patent. The USPTO determined that Exela lacked standing to seek such relief. Exela also seeks declaratory judgment that the USPTO's rules and regulations that allow for revival of abandoned, international patent applications under the "unintentional" standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. Our motion to intervene in this lawsuit was granted in October 2012. In December 2012, the district court dismissed the case with prejudice as barred by the applicable statute of limitations. In February 2013, Exela appealed the district court's decision to the Court of Appeals for the Federal Circuit. The Court of Appeals heard oral argument on the appeal in February 2014. A decision by the Court of Appeals in favor of Exela could result in the invalidation of the '218 patent.

Stockholder Class-Action Litigation Regarding Our Pending Acquisition by Mallinckrodt plc

Following the February 11, 2014, announcement that we had entered into an agreement and plan of merger with Mallinckrodt and Merger Sub, six putative class-action lawsuits were filed in the Court of Chancery of the State of Delaware: *Wolfson v. Cadence Pharmaceuticals, Inc., et al.*, No. 9341-VCP (filed February 12, 2014); *Goode v. Garner, et al.*, No. 9361-VCP (filed February 18, 2014); *Bushansky v. Cadence Pharmaceuticals Inc., et al.*, No. 9365-VCP (filed February 19, 2014); *Bokol v. Cadence Pharmaceuticals Inc., et al.*, No. 9367 (filed February 19, 2014); *Elvir v. Cadence Pharmaceuticals Inc., et al.*, No. 9370-VCP (filed February 19, 2014); and *Nguyen v. Cadence Pharmaceuticals, Inc., et al.*, No. 9376-VCP (filed February 21, 2014). Two substantially identical putative class-action lawsuits were filed in the Superior Court of California, County of San Diego: *Denny v. Cadence Pharmaceuticals, Inc., et al.*, No. 37-2014-00002579-CU-BT-CTL (filed February 13, 2014) and *Militello v. Cadence Pharmaceuticals, Inc., et al.*, No. 37-00003634-CU-BT-CTL (filed February 20, 2014). The complaints allege that members of our board of directors breached their fiduciary duties to our stockholders in connection with the proposed transaction and that the merger agreement involves an unfair price, an inadequate sales process, and unreasonable deal protection devices that purportedly preclude competing offers. The complaints other than *Bushansky* further allege that we, Mallinckrodt, and/or Merger Sub aided and abetted the alleged breaches of fiduciary duties. The lawsuits seek an injunction against the consummation of the merger and rescission of the merger agreement to the extent the merger may already be consummated prior to the entry of the court's final judgment, and an award of costs and expenses, including attorneys' and experts' fees.

We intend to vigorously defend against these claims. The outcome of this litigation cannot be predicted at this time and any outcome in favor of the plaintiffs could have an adverse effect on the proposed transaction, our financial condition, and our results of operations.

Research and Development

Our research and development expenses were \$6.7 million in 2013, \$6.5 million in 2012 and \$8.9 million in 2011. Our historical research and development expenses relate predominantly to OFIRMEV and, prior to 2011, 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.

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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, we began enrollment in our FDA-required post-approval clinical trial for OFIRMEV in pediatric patients under two years of age during the third quarter of 2012, which we plan to complete by August 2015. We may also conduct clinical studies to expand the indications for OFIRMEV. In addition, in July 2012, we filed a New Drug Submission for OFIRMEV with Health Canada which was accepted for review in August 2012. In June 2013, Health Canada issued a Notice of Compliance that granted marketing approval for OFIRMEV in Canada. We have not determined the commercial feasibility of launching the product in Canada, either independently or in collaboration with a company with an existing Canadian commercial presence, because we have not yet received a pricing review from the Canadian Patented Medicine Prices Review Board, or the PMPRB. We submitted a pricing review application for OFIRMEV to the PMPRB in October 2013. We expect to incur costs associated with any marketing activities that may take place in Canada. 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.

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.

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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 from the filing date 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 will issue an approval letter. 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, or CRL. The CRL usually describes the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the CRL typically contains the conditions that must be met in order to secure final approval of the NDA. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. 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.

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 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

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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 disease or 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. If fast track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. In some cases, a fast track product may be eligible for accelerated approval, pursuant to which the product is approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. 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 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 began enrolling patients in the third quarter of 2012 in 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 current 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 fraud and abuse laws, including the anti-kickback statute and false claims laws and regulations. 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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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. There are also federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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 statute 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.

Further, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty of fraud or false claims under PPACA without actual knowledge of the statute or specific intent to violate it. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

The PPACA also imposes new reporting and disclosure requirements on device and drug manufacturers for any “transfer of value” made or distributed to prescribers and other healthcare providers. In addition, device and drug manufacturers are now required to report and disclose any 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 of up to an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Also, as of August 1, 2013, manufacturers are required to begin data collection and will be required to report such data to CMS by March 31, 2014, and by the 90th day of every subsequent calendar year for the reporting period of the previous year.

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. Meanwhile, 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.

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

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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 any contract manufacturers or 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.

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 customers 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 received by our customers may not be 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. In March 2010, the PPACA became law and made 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. The PPACA seeks to expand health care coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid for certain outpatient drugs, 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 promotes programs that increase the federal government's comparative effectiveness research, which may be used to evaluate the selection of medical services by clinicians and others. In addition, PPACA implements payment system reforms such as a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models, and creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projections of such spending exceed a specified growth rate.

Other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the

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legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, the President signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws, as well as legislative and regulatory proposals that may be adopted from time to time in the future, may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Employees

As of February 21, 2014, we had approximately 210 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 Pending Acquisition by Mallinckrodt plc

The announcement and pendency of the acquisition by Mallinckrodt of us pursuant to a tender offer and subsequent merger of us with a wholly-owned indirect subsidiary of Mallinckrodt could have an adverse effect on our stock price and/or our business, financial condition, results of operations or business prospects.

The announcement and pendency of the Mallinckrodt tender offer and merger could disrupt our business in the following ways, among others:

- third parties may determine to delay or defer purchase decisions with regard to our product or terminate and/or attempt to renegotiate their relationships with us as a result of the Mallinckrodt tender offer and merger, whether pursuant to the terms of their existing agreements with us or otherwise;
- the attention of our management may be directed toward the completion of the Mallinckrodt tender offer and merger and related matters, and their focus may be diverted from the day-to-day business operations of our company, including from other opportunities that might otherwise be beneficial to us; and
- current and prospective employees may experience uncertainty regarding their future roles with Mallinckrodt, which might adversely affect our ability to retain, recruit and motivate key personnel and may adversely affect the focus of our employees on sales of our product.

Should they occur, any of these matters could adversely affect our stock price or harm our financial condition, results of operations or business prospects.

Our executive officers and directors may have interests that are different from, or in addition to, those of our stockholders generally.

Our executive officers and directors may have interests in the Mallinckrodt tender offer and merger that are different from, or are in addition to, those of our stockholders generally. These interests include direct or indirect ownership of our common stock, stock options and restricted stock units, and the potential receipt of change in control or other severance payments in connection with the proposed tender offer and merger.

The Merger Agreement contains provisions that could discourage or make it difficult for a third party to acquire us prior to the completion of the Mallinckrodt tender offer and the merger.

The Merger Agreement contains provisions that make it difficult for us to entertain a third-party proposal for an acquisition of our company. These provisions include our agreement not to solicit or initiate any additional discussions with third parties regarding other proposals for our acquisition, as well as restrictions on our ability to respond to such proposals, subject to fulfillment of certain fiduciary requirements of our board of directors. The Merger Agreement also contains certain termination rights, including, under certain circumstances, a requirement for us to pay to Mallinckrodt a termination fee of approximately \$20.2 million, or approximately 1.5% of the purchase price.

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These provisions might discourage an otherwise-interested third party from considering or proposing an acquisition of our company, even one that may be deemed of greater value to our stockholders than the Mallinckrodt offer. Furthermore, even if a third party elects to propose an acquisition, the concept of a termination fee may result in that third party's offering of a lower value to our stockholders than such third party might otherwise have offered.

Obtaining required approvals necessary to satisfy the conditions to the completion of the Mallinckrodt tender offer and the merger may delay or prevent completion of the proposed acquisition.

The completion of the Mallinckrodt tender offer and the merger are conditioned upon the expiration or termination of the waiting period under the HSR Act. We intend to pursue all required approvals in accordance with the Merger Agreement. However, no assurance can be given that the required approvals will be obtained and, even if all such approvals are obtained, no assurance can be given as to the terms, conditions and timing of the approvals or that they will satisfy the terms of the Merger Agreement.

Litigation may be filed against us and the members of our board of directors challenging the Mallinckrodt tender offer and merger and an adverse judgment in any such lawsuit may prevent the Mallinckrodt tender offer and merger from being completed within the expected timeframe or at all.

Historically, following the announcement of a proposed merger, securities class action litigation has often been brought against a company and its board of directors, and similar lawsuits have been filed against us relating to the Mallinckrodt tender offer and merger. Any adverse judgment in this litigation or any other such litigation may prevent the tender offer and the merger from being completed within the expected timeframe or at all.

Failure to complete the Mallinckrodt tender offer and the merger could negatively impact our business, financial condition, results of operations or our stock price.

The completion of the Mallinckrodt tender offer and merger are subject to a number of conditions, including the tender of a sufficient number of shares held by our current stockholders pursuant to the tender offer and clearance under the HSR Act, and there can be no assurance that the conditions to the completion of the tender offer and the merger will be satisfied. The Merger Agreement may also be terminated by us and Mallinckrodt in certain specified circumstances, including, subject to compliance with the terms of the Merger Agreement, by us in order to accept a third-party acquisition proposal that our board of directors determines constitutes a superior proposal upon payment of a \$20.2 million termination fee to Mallinckrodt. If the tender offer and the merger are not completed, we will be subject to several risks, including:

- the current trading price of our common stock may reflect a market assumption that the merger will be completed;
- certain of our executive officers, employees and/or directors may seek other opportunities;
- we expect to incur substantial transaction costs in connection with the tender offer and the merger whether or not they are completed; and
- under the Merger Agreement, we are subject to certain restrictions on the conduct of our business prior to the completion of the merger, which restrictions could adversely affect our ability to realize certain of our business strategies or take advantage of certain business opportunities.

If the tender offer and the merger are not completed, these risks may materialize and materially and adversely affect our business, financial condition, results of operations or our stock price.

Risks Related to Our Business and Industry

Our success depends on the commercial success of our only product, OFIRMEV.

Our success depends on the continued success of our efforts to 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 maintain and increase revenues from sales of OFIRMEV will depend on several factors, including:

- our ability to increase 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 maintain and defend our patent protection and regulatory exclusivity for OFIRMEV;
- our ability to continue to procure a supply of OFIRMEV from our sole source third-party manufacturer in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;
- the performance of our third-party manufacturer and our ability to ensure that our supply chain for OFIRMEV efficiently and consistently delivers OFIRMEV to our customers;
- our ability to continue to deploy and support a qualified sales force;
- our ability to maintain fees and discounts payable to the wholesalers and distributors who distribute OFIRMEV, as well as to group purchasing organizations, at commercially reasonable levels;
- whether the FTC, DOJ or third parties seek to challenge and are successful in challenging our settlement agreements with Perrigo and Sandoz;
- warnings or limitations that we may be required to add to OFIRMEV's FDA-approved labeling;
- the occurrence of adverse side effects or inadequate therapeutic efficacy of OFIRMEV, and any resulting product liability claims or product recalls; and
- our ability to achieve hospital formulary acceptance for OFIRMEV, and to the extent third-party payors separately cover and reimburse for OFIRMEV, the availability of adequate levels of reimbursement 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.

The continued success of our commercialization of OFIRMEV is subject to many internal and external challenges and if we cannot overcome these challenges in a timely manner, our 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 provide effective promotional materials to our sales force and medical and scientific support materials for our medical affairs staff for their use in communicating about 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. The effectiveness of our promotional and medical communication materials about OFIRMEV is critically important to our efforts to inform and educate potential customers about the benefits and risks of OFIRMEV and its proper administration, and the continued success of our commercialization activities for the product.

In addition to extensive internal efforts, the continued successful commercialization of OFIRMEV requires many third parties, over whom we have no control, to decide to utilize OFIRMEV and to make it readily

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available at the point of care throughout their hospitals. These third parties include physicians, pharmacists, and hospital pharmacy and therapeutics committees, which are commonly referred to as 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, either initially or later, when the increasing use of OFIRMEV within their institution begins to significantly impact their budgets. 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 maintain and grow hospital sales of OFIRMEV.

We have no manufacturing capabilities and depend entirely upon our sole source contract manufacturer to produce OFIRMEV. If our contract manufacturer fails to meet our requirements for OFIRMEV, or fails 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 contract manufacturers as our source for OFIRMEV.

In February 2013, we amended our supply agreement with Lawrence Laboratories, an operating division of Swords Laboratories and a member of the BMS group of companies, under which BMS Anagni, an indirect subsidiary of BMS located in Anagni, Italy, manufactures OFIRMEV for us on behalf of Lawrence Laboratories. BMS Anagni has manufactured the product for more than ten years for sale and distribution by BMS and its affiliates in a number of countries outside of the U.S. and Canada. Any termination or disruption of our relationship with BMS Anagni, which is currently our sole source for OFIRMEV, may materially harm our business and financial condition and adversely impact our commercialization and sales efforts with respect to the product.

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. If our contract manufacturer or API supplier, or any other supplier of critical components for OFIRMEV, becomes unable to meet our supply requirements, the process of changing or adding a new contract manufacturer or critical component supplier 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.

In March 2013, we entered into an agreement with Grifols for the development, manufacture and supply of commercial quantities of OFIRMEV in flexible plastic bags. We submitted a supplemental NDA to the FDA in December 2013 seeking approval of the product to be manufactured by Grifols, but Grifols will not be able to supply us with OFIRMEV until FDA approval is granted, if ever.

Any contract manufacturer for OFIRMEV must comply with strictly enforced federal, state and foreign regulations, including GMP regulations. The FDA will inspect a contract manufacturer's facilities from time to time and, in the event that any such inspection reveals that the facility is not in compliance with applicable

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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.

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 relatively new product in the U.S., the effect of any delay or failure to deliver could be magnified due to the short sales track record for OFIRMEV.

For example, in 2012, we announced two voluntary recalls of OFIRMEV manufactured by Baxter, our previous contract manufacturer, due to the presence of unidentified, visible particles in a limited number of vials of the product, which were detected during routine stability testing. Although we received no adverse event reports associated with the particulate matter or product complaints involving similar particulate matter, as a precautionary measure we suspended production by Baxter in connection with the initial recall and decided to recall all remaining lots of OFIRMEV manufactured by Baxter in connection with the second recall. Additionally, following the first recall, some of our customers experienced short-term supply delays due to the suspension of shipments from Baxter until we were able to expedite sufficient shipments of OFIRMEV from BMS Anagni, and we incurred higher freight costs associated with the expedited product shipments. We also incurred unabsorbed manufacturing costs during the time that Baxter's manufacturing of the product was suspended. As a result of the second recall, we destroyed the Baxter-manufactured finished product inventory that we previously placed on indefinite hold, and recorded charges of \$5.8 million in relation to this product. In March 2013, we and Baxter mutually agreed to terminate our supply agreement for OFIRMEV. Under the termination agreement, we were required to remove our manufacturing equipment from Baxter's facility within 180 days and pay Baxter for any pre-approved costs or expenses related to such removal. As a result, we incurred impairment charges of \$7.7 million and a loss on the sale of equipment of \$0.9 million during the fourth quarter of 2012 in relation to the assets involved with the manufacture of OFIRMEV under the terminated development and supply agreement with Baxter.

In addition, in July 2013, we voluntarily issued a letter to our customers requesting that they inspect their inventories of OFIRMEV to ensure that each vial includes a lot number and expiration date, following our receipt of a small number of customer reports of vials where such information was missing. We have received no reports of adverse events associated with this issue, and have notified FDA of our voluntary notification to our customers. Corrective actions have been implemented by our contract manufacturer to prevent a reoccurrence.

Any future recalls of OFIRMEV 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 and equipment.

If OFIRMEV does not achieve sufficient 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 or 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

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- 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 or product candidate 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 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 or product candidates we may license or acquire. If OFIRMEV, or any other product or 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 or product candidate 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 products or product candidates we may license or acquire and may have to limit their commercialization.

The use of OFIRMEV and any other products or 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 products or product candidates;
- loss of revenues;

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- 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 products or 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.

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 non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the U.S. from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, is available for the treatment of pain and fever in adults and children 17 years of age and older. 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 IV 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.

Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research development resources, including personnel and technology;

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- 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.

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, maintain our sales force and commercial infrastructure and commercialize OFIRMEV;
- purchase sufficient quantities of OFIRMEV from our contract manufacturer to meet customer demand or our minimum purchase obligations;
- complete our ongoing efficacy, pharmacokinetic and pharmacodynamic study of OFIRMEV in pediatric patients under two years of age, as required to comply with our post-commercialization commitment to the FDA; or
- acquire or in-license additional 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 maintaining our sales force and commercial infrastructure, may be greater than anticipated;
- we may incur unexpected costs in order to ensure a sufficient supply of OFIRMEV from our contract manufacturer 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 or maintain lawsuits to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of IV acetaminophen, such as our ongoing intellectual property 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, we have refinanced

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our \$30.0 million secured credit facility with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation on various occasions, including most recently in December 2012. 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 participation in 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 intellectual property litigation, which could decrease sales of this product and have a material adverse effect on our financial condition, stock price and operations.

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. 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.

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) by January 2014, and in January 2014, the FDA further recommended that healthcare professionals discontinue prescribing and dispensing prescription combination drug products that contain more than 325 mg of acetaminophen in each dosage unit in order to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In the January 2011 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 from all routes of administration. Similarly, after discussions with the FDA, we added a boxed warning to the prescribing information for OFIRMEV in October 2013 regarding the potential for dosing errors with OFIRMEV and the risk of liver injury associated with the administration of acetaminophen (by all routes of administration) at doses that exceed the recommended maximum daily limits. 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. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. We cannot predict whether the FDA will require additional warnings, or place any additional limitations on our ability to advertise and promote OFIRMEV, which could negatively impact our sales of OFIRMEV. The OFIRMEV prescribing information was also updated in accordance with a drug safety communication issued by the FDA in August 2013 requiring a warning that acetaminophen has been associated with a risk of rare but serious skin reactions, such as

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Stevens-Johnson Syndrome, toxic epidermal necrolysis and acute generalized exanthematous pustulosis, which can be fatal. The FDA indicated that it will require that this warning be added to the labels of all prescription drug products containing acetaminophen to address this risk, and will request or encourage manufacturers of over-the-counter acetaminophen drug products to do the same. Similar warnings are also required for other medications used to treat pain or fever, including NSAIDs.

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, FDAAA 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 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.

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, concerns regarding a product’s safety, the discovery of previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where a product is manufactured, may result in the imposition of additional restrictions, including withdrawal of the product from the market. For example, after discussions with the FDA, we added a boxed warning to the prescribing information for OFIRMEV in October 2013 regarding the potential for dosing errors with OFIRMEV and the risk of liver injury associated with the administration of acetaminophen (by all routes of administration) at doses that exceed the recommended maximum daily limits.

In addition, as a condition of the approval of OFIRMEV, we are required to complete an efficacy, pharmacokinetic and pharmacodynamic study 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. Enrollment in this study began in the third quarter of 2012. The FDA has agreed to a due date for completion of this study in August 2015.

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;

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- 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 the federal anti-kickback statute and false claims laws and regulations. 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 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. 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. There are also federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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 statute 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, results of operations and growth prospects. Further, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty of fraud or false claims under PPACA without actual knowledge of the statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

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The PPACA also imposes new reporting and disclosure requirements on device and drug manufacturers for any “transfer of value” made or distributed to prescribers and other healthcare providers. In addition, device and drug manufacturers are now required to report and disclose any 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 of up to an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Also, as of August 1, 2013, manufacturers are required to begin data collection and will be required to report such data to CMS by March 31, 2014, and by the 90th day of every subsequent calendar year for the reporting period of the previous year.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the costs associated with implementing and maintain such systems, and the possibility that a healthcare company may run afoul of one or more of the requirements.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

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 a drug 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 a product 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 PPACA became law and made 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

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effective immediately and others of which will be taking effect over the next several years. The PPACA seeks to expand health care coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA also imposes 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 promotes programs that increase the federal government's comparative effectiveness research, which may be used to evaluate the selection of medical services by clinicians and others. In addition, PPACA implements payment system reforms such as a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models, and creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projections of such spending exceed a specified growth rate.

Other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, the 2% Medicare payment reductions went into effect. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws, as well as legislative and regulatory proposals that may be adopted from time to time in the future, may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations. 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.

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.

We may never be successful in our efforts to commercialize OFIRMEV in Canada.

Our rights to OFIRMEV include Canada, as well as the United States. In June 2013, Health Canada issued a Notice of Compliance that granted marketing approval for OFIRMEV in Canada, and we initiated a pricing review for the product with the Canadian Patented Medicine Prices Review Board in October 2013. Following the completion of the pricing review process, we will assess the commercial feasibility of launching the product in Canada, either independently or in collaboration with a company with an existing Canadian commercial presence. Additionally, in order to market OFIRMEV in Canada, we must comply with numerous and varying Canadian regulatory requirements regarding non-clinical testing, manufacturing, clinical safety, efficacy and marketing. Our ability to successfully commercialize OFIRMEV in Canada will depend significantly on the price we are able to charge for the product and our ability to establish cost-effective marketing and sales capabilities and distribution channels for Canada. If the pricing for the product is not sufficient, we may elect to not market OFIRMEV in Canada, or if we do market the product, any profits we generate may be limited.

If our hospital customers fail to receive adequate reimbursement from the government or third-party payors 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 reimbursement rates our customers receive for OFIRMEV. 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 products. In addition, some third-party payors, including government health programs such as Medicare, managed care providers and commercial 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.

OFIRMEV or any other products or 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 and accordingly, we may be unable 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 or after our marketed products have been approved. 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 products or product candidates we may license or acquire from hospital formularies, or lower the prices we would receive for our products or 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 sell 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 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 sell this product 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 commercial efforts.

If BMS breaches the underlying agreement under which we sublicense the rights to OFIRMEV, we could lose the ability to sell 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 commercial efforts for OFIRMEV.

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

As of February 21, 2014, we had approximately 210 employees. 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 expertise of our senior management, particularly Theodore R. Schroeder, our President and Chief Executive 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 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, 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. Any attempt to develop new products in the future could be limited unless we were able to hire a suitable replacement.

In addition, we have scientific and clinical advisors who assist us in 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 set back.

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 IV formulation of acetaminophen. As a result, our market opportunity for this product may be limited by the lack of patent protection for the active ingredient itself and other formulations of IV acetaminophen 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 Canadian patents owned by Pharmatop, under BMS's license to these patents from Pharmatop. U.S. Patent No. 6,028,222, or the '222 patent (Canadian patent number 2,233,924), covers the formulation of OFIRMEV, and this patent expires in August 2017. U.S. Patent No. 6,992,218, or the '218 patent (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 of OFIRMEV within the period agreed on with the FDA, which is August 2015, and, upon timely completion and the acceptance by the FDA of the data from this study, we expect that OFIRMEV will be eligible for an additional six months of marketing exclusivity in the U.S.

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. We are also 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 OFIRMEV 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.

Five 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. If a third party files an NDA or ANDA for a generic drug product containing acetaminophen and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that, 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 NDA or 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 NDA or 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 NDA or 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 NDA or ANDA will not be subject to the 30-month stay.

For example, in August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Perrigo and Exela. The lawsuit followed the notices that we received in July 2011 from each

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of Perrigo and Exela concerning their filings of ANDAs containing a “Paragraph IV” patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit, we alleged that Perrigo and Exela 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 Perrigo 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 Perrigo or Exela, or such shorter or longer period as the Court may order. Each of Perrigo and Exela filed an answer in the case that asserted, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims.

We settled with Perrigo and the case against Perrigo was dismissed on November 30, 2012. In connection with the settlement and license agreements entered into in November 2012, Perrigo was granted the exclusive right of first refusal to negotiate an agreement with us to market an authorized generic version of OFIRMEV in the U.S. in the event that we elect to launch an authorized generic version of the product. The license agreement also provides that, if we enter into an agreement for Perrigo to market an authorized generic version of OFIRMEV during the license period, Perrigo would purchase the product exclusively from us. We would receive product costs plus an administrative fee, as well as a royalty payment based on the net profits achieved by Perrigo from the sale of the authorized generic product. Additionally, we granted Perrigo the non-exclusive right to market a generic IV acetaminophen product in the U.S. under Perrigo’s ANDA after December 6, 2020, or earlier under certain circumstances. The FTC or the DOJ could seek to challenge our settlement with Perrigo, or a competitor, customer or other third-party could initiate a private action under antitrust or other laws challenging our settlement with Perrigo. Any such challenge could be both expensive and time consuming and may render the settlement agreement unenforceable.

A bench trial for the lawsuit with Exela was held in May 2013, with one additional trial date held in early July 2013. In November 2013, the court ruled in favor of us and found that Exela’s ANDA for a generic version of OFIRMEV infringed the ‘222 and ‘218 patents. An appeal of the decision in favor of us was filed by Exela on December 20, 2013. It is not possible to predict the outcome of this appeal, and an adverse outcome could result in the launch of one or more generic versions of OFIRMEV before the expiration of the last of the listed patents in June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted), which could adversely affect our ability to successfully maximize the value of OFIRMEV, and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

In addition, in January 2013, we filed suit in the United States District Court for the Southern District of California against Fresenius Kabi USA, LLC, or Fresenius, following receipt of a December 2012 notice from Fresenius concerning its submission of an NDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In February 2013, we filed suit in the United States District Court for the Southern District of California against Sandoz, Inc., or Sandoz, following receipt of a December 2012 notice from Sandoz concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In October 2013, we filed a motion to amend our complaint against Sandoz to join Sandoz AG, Neogen International N.V., APC Pharmaceuticals, LLC, and DIACO S.p.A. (together with Sandoz, the Sandoz Parties) to the lawsuit against Sandoz due to the involvement of each of these companies with the preparation of the Sandoz ANDA and related matters. In the lawsuits against Fresenius and the Sandoz Parties, which were coordinated for purposes of discovery and other pretrial proceedings in the Southern District of California, we alleged that Fresenius and the Sandoz Parties each infringed the ‘222 patent and the ‘218 patent by filing an NDA, in the case of Fresenius, or an ANDA, in the case of the Sandoz Parties, seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Both Fresenius and the Sandoz Parties filed answers in the Southern District of California asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims. Both the Fresenius and

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Sandoz lawsuits were filed within 45 days of receipt of the respective notice letters, thereby triggering a stay of FDA approval of the Fresenius NDA and the Sandoz 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 Fresenius and/or the Sandoz Parties, or such shorter or longer period as the court may order.

In January 2014, we entered into a settlement agreement and a binding term sheet for a license agreement with the Sandoz Parties. The settlement agreement includes a stipulation by the parties requesting dismissal with prejudice of the lawsuit filed by us relating to the ANDA filed by Sandoz. Under the terms of the license, we granted to the holder of the Sandoz ANDA and its affiliates the non-exclusive right to market a generic intravenous acetaminophen product in the United States under the Sandoz ANDA beginning December 6, 2020, or earlier under certain circumstances. We also agreed that in the event that we determine to launch an authorized generic version of OFIRMEV (i.e., a generic version marketed under our NDA) in the U.S. and Perrigo elects not to exercise its right of first refusal to become the distributor of the authorized generic version of the product, we will grant a similar right of first refusal to the holder of the Sandoz ANDA on substantially the same terms as those previously granted to Perrigo. In addition, the license agreement will contain provisions regarding indemnification, confidentiality and other customary provisions for agreements of these kinds. The settlement documents are subject to submission to the Federal Trade Commission and the U.S. Department of Justice. Litigation remains ongoing against Fresenius, and the bench trial for such lawsuit is tentatively scheduled to commence on July 14, 2014.

In December 2013, we received a notice from Wockhardt USA LLC, or Wockhardt, stating that Wockhardt filed an ANDA containing a Paragraph IV patent certification with the FDA for a generic version OFIRMEV. This notice stated that the Paragraph IV patent certification was made with respect to both the '222 patent and the '218 patent. We filed suit against Wockhardt Limited, Wockhardt BIO AG and Wockhardt on January 22, 2014 in the U.S. District Court of Delaware, and on January 23, 2014, in the U.S. District Court of New Jersey.

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 without our consent 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 intend to vigorously enforce our intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products without our consent prior to the expiration of our patents. However, given the unpredictability inherent in litigation, we cannot predict or guarantee the outcome of these matters or any other litigation. Regardless of how these matters are ultimately resolved, these matters may be costly, time-consuming and distracting to our management, which could have a material adverse effect on our business.

The protection of our intellectual property rights is critical to our success and any failure on our part to adequately secure such rights would materially affect our business.

Our commercial success depends on maintaining patent protection and trade secret protection for OFIRMEV, as well as for any other products or product candidates that we may license or acquire, and 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.

For example, in April 2012, Exela filed suit against David J. Kappos and the USPTO in the United States District Court for the Eastern District of Virginia for declaratory judgment seeking a reversal of the USPTO's decision not to act on a petition by Exela to vacate the USPTO's April 2003 order reviving the international

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application for the '218 patent. The lawsuit followed the USPTO's rejection of Exela's petition to the USPTO filed in November 2011, which sought to vacate the April 23, 2003 order granting Pharmatop's petition to revive the '218 patent. The USPTO determined that Exela lacked standing to seek such relief. Exela also seeks declaratory judgment that the USPTO's rules and regulations that allow for revival of abandoned, international patent applications under the "unintentional" standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. Our motion to intervene in this lawsuit was granted in October 2012. In December 2012, the district court dismissed the case with prejudice as barred by the applicable statute of limitations. In February 2013, Exela appealed the district court's decision to the Court of Appeals for the Federal Circuit. Oral argument was held on February 3, 2014. A decision by the Court of Appeals in favor of Exela could result in the invalidation of the '218 patent.

Additionally, in September 2012, an unidentified third party (subsequently identified as Exela) filed with the USPTO a Request for Ex Parte Reexamination of the '222 patent. In December 2012, we received notice that the USPTO had granted the Request for Reexamination. The reexamination process is provided for by law and requires the USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO. In February 2013, we and Pharmatop filed with the USPTO a patent owner's statement commenting on the reexamination request, and in April 2013, Exela filed comments in response to the patent owner's statement. In a non-final, initial office action issued by the USPTO on August 13, 2013, the USPTO rejected certain claims of the '222 patent. A response to the first office action was filed in November 2013.

In addition, in January 2014, an unidentified third party filed with the USPTO a Request for Ex Parte Reexamination of the '218 patent. All of the claims of the '222 and '218 patents remain valid and in force during the reexamination proceedings. Because we and Pharmatop believe that the scope and validity of the patent claims in these patents are appropriate and that the USPTO's prior issuances of the patents were correct, we, in conjunction with Pharmatop, will vigorously defend these patents. We cannot predict whether we and Pharmatop ultimately will succeed in maintaining the scope and validity of the claims of these patents during reexamination. If any of the patent claims in these patents ultimately are narrowed during prosecution before the USPTO, the extent of the patent coverage afforded to OFIRMEV could be impaired, which could potentially harm our business and operating results.

On November 4, 2013, we submitted a citizen petition to the FDA requesting that the FDA refrain from approving any new acetaminophen product for parenteral use that does not have an identical inactive ingredient profile as OFIRMEV without nonclinical studies and adequate and well-controlled clinical trials demonstrating the product is as safe and effective as OFIRMEV. The FDA is required by statute to issue a response to our citizen petition within 150 days, or no later than April 3, 2014; however, we cannot predict when or if the FDA will issue a final response to, or otherwise take any other action with respect to, our petition.

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

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

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;

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- others may independently develop similar or alternative technologies or duplicate any of our products, 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 products or 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 products or product candidates. In the event that a third party has also filed a U.S. patent application relating to our products or product candidates or a similar invention, we may have to participate in interference proceedings declared by the USPTO 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 products or product candidates. Even if patents are issued, 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 or 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.

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. Pharmatop is under a contractual obligation to BMS to maintain the issued OFIRMEV patents in the U.S. and Canada. BMS has the opportunity to consult, review and comment on any patent office communications.

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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 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 effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management.

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 products or product candidates that we may license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of pain treatment and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse effect 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;

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- 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, omigagan 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 \$24.3 million, \$81.0 million, and \$93.0 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of \$472.0 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 have decreased since 2010 due to the completion of our clinical development program for OFIRMEV, our sales, marketing, manufacturing and legal expenses have increased significantly since that time in connection with the commercialization OFIRMEV. In addition, we are required to pay a royalty on net sales of OFIRMEV, which includes minimum obligations, and we may be required to make future milestone payments upon the achievement of certain net sales levels of OFIRMEV. We also have minimum purchase obligations under our supply agreement with our contract manufacturer for OFIRMEV. As a result, we expect to continue to incur operating losses until we are able to generate sufficient revenues to operate profitably. Because of the numerous risks and uncertainties associated with developing and marketing 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 or procure 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 or product candidates that we may license or acquire.

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We have incurred and anticipate continuing to incur significant costs associated with our efforts to commercialize, market and sell OFIRMEV, and we are not generating sufficient revenues to operate profitably. If we are unable to generate sufficient 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. 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. The revenues we have generated from OFIRMEV have changed significantly since launch, and we anticipate that they will continue to change. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a longer history of marketing OFIRMEV or other 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;
- the level of underlying hospital demand for OFIRMEV and wholesalers' buying patterns;
- 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 arrangements;
- 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;
- our ability to successfully defend the patents for OFIRMEV and maintain our market exclusivity;
- our ability to successfully procure sufficient quantities of OFIRMEV and maintain adequate supply levels;
- regulatory developments affecting OFIRMEV or the products or product candidates of our competitors;
- costs associated with any product recalls or investigations into quality concerns; and
- variations in the level of expenses related to our development programs for any future product candidates and any further development costs associated with OFIRMEV, including our ongoing pediatric clinical trial.

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

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through which we issued a total of 12.5 million shares of common stock 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, we have refinanced our \$30.0 million secured credit facility with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation on various occasions, including most recently in December 2012. This secured credit facility contains a variety of affirmative and negative covenants, including minimum quarterly product revenue requirements, 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 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”

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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, 2013, we had generated federal and state net operating loss carryforwards of approximately \$392.1 million and \$387.6 million, respectively. We also had federal and state research and development tax credit carryforwards of approximately \$4.1 million and \$2.5 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 2025 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 have completed an analysis through December 31, 2012, and determined that we experienced an ownership change in March 2006. However, this ownership change did not result in the forfeiture of any net operating loss carryforwards or research tax credits. Therefore, we have reinstated the (1) deferred tax assets for net operating losses of approximately \$149.1 million and (2) research and development credits of approximately \$6.8 million generated through 2012 to our deferred tax asset schedule. Further, we have recorded a corresponding increase to our valuation allowance. The analysis did not have any impact on our unrecognized tax benefits. There is risk that additional changes in ownership have occurred since the completion of our analysis, which was through December 31, 2012. If a change in ownership were to have occurred, additional net operating loss and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

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, and the U.S. mortgage market in the U.S. have contributed to increased volatility and shifting expectations for the economy and the markets going forward. These factors, combined with volatile commodity 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 changes 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.

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The trading prices for our common stock during the 52 weeks ending December 31, 2013 ranged from a high of \$10.09 to a low of \$4.45. 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;
- 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 intellectual property lawsuits relating to OFIRMEV, including any future lawsuits, 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 products or potential products, including concerns about the boxed warning in the prescribing information for OFIRMEV;
- 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 the amount of reimbursement received by our customers;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

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

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

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

For example, 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

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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, 2013, our executive officers and directors and their affiliates together controlled approximately 27% 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.

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. Our amended and restated bylaws also provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders. 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,

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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*

Effective January 1, 2014, we expanded the space that we lease for our headquarters in San Diego, California, from 16,600 square feet to approximately 23,750 square feet. Our current lease term expires in May 2019, and we have the right to renew the lease for one additional five-year period. We have no laboratory, research, manufacturing or warehouse facilities. 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*

'222 and '218 Patent Litigation: Exela Pharma Sciences, LLC and Paddock Laboratories, Inc. (Perrigo Company)

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 Perrigo, and against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc., collectively referred to herein as Exela. The lawsuit followed the notices that we received in July 2011 from each of Perrigo and Exela concerning their filings of ANDAs containing a "Paragraph IV" patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit, we alleged that Perrigo and Exela 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

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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 Perrigo 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 Perrigo or Exela, or such shorter or longer period as the Court may order. Each of Perrigo and Exela filed an answer in the case that asserted, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims.

We settled with Perrigo and the case against Perrigo was dismissed on November 30, 2012. In connection with the settlement and license agreements entered into in November 2012, Perrigo was granted the exclusive right of first refusal to negotiate an agreement with us to market an authorized generic version of OFIRMEV in the U.S. in the event that we elect to launch an authorized generic version of the product. The license agreement also provides that, if we enter into an agreement for Perrigo to market an authorized generic version of OFIRMEV during the license period, Perrigo would purchase the product exclusively from us. We would receive product costs plus an administrative fee, as well as a royalty payment based on the net profits achieved by Perrigo from the sale of the authorized generic product. Additionally, we granted Perrigo the non-exclusive right to market a generic IV acetaminophen product in the U.S. under Perrigo's ANDA after December 6, 2020, or earlier under certain circumstances. The Federal Trade Commission, or FTC, or the Department of Justice, or DOJ, could seek to challenge our settlement with Perrigo, or a competitor, customer or other third-party could initiate a private action under antitrust or other laws challenging our settlement with Perrigo.

A bench trial for the lawsuit with Exela was held in May 2013, with one additional trial date held in early July 2013. In November 2013, the court ruled in favor of us and found that Exela's ANDA for a generic version of OFIRMEV infringed the '222 and '218 patents. An appeal of the decision in favor of us was filed by Exela on December 20, 2013. It is not possible to predict the outcome of this appeal, and an adverse outcome could result in the launch of one or more generic versions of OFIRMEV before the expiration of the last of the listed patents in June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted), which could adversely affect our ability to successfully maximize the value of OFIRMEV, and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

'222 and '218 Patent Litigation: Fresenius Kabi USA, LLC, Sandoz, Inc. and Wockhardt USA LLC

In January 2013, we filed suit in the United States District Court for the Southern District of California against Fresenius Kabi USA, LLC, or Fresenius, following receipt of a December 2012 notice from Fresenius concerning its submission of a New Drug Application, or NDA, containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In February 2013, we filed suit in the United States District Court for the Southern District of California against Sandoz, Inc., or Sandoz, following receipt of a December 2012 notice from Sandoz concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In October 2013, we filed a motion to amend our complaint against Sandoz to join Sandoz AG, Neogen International N.V., APC Pharmaceuticals, LLC, and DIACO S.p.A. (together with Sandoz, the Sandoz Parties) to the lawsuit against Sandoz due to the involvement of each of these companies with the preparation of the Sandoz ANDA and related matters.

In the lawsuits against Fresenius and the Sandoz Parties, which were coordinated for purposes of discovery and other pretrial proceedings in the Southern District of California, we alleged that Fresenius and the Sandoz Parties each infringed the '222 patent and the '218 patent by filing an NDA, in the case of Fresenius, or an ANDA, in the case of the Sandoz Parties, seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Both Fresenius and the Sandoz Parties filed answers in the Southern District of California asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims. Both the Fresenius and Sandoz lawsuits were filed within 45 days of receipt of the respective notice letters, thereby triggering a stay of FDA approval of the Fresenius NDA and the Sandoz 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 Fresenius and/or the Sandoz Parties, or such shorter or longer period as the court may order.

In January 2014, we entered into a settlement agreement and a binding term sheet for a license agreement with the Sandoz Parties. The settlement agreement includes a stipulation by the parties requesting dismissal with prejudice of the lawsuit filed by us relating to the ANDA filed by Sandoz. Under the terms of the license, we granted to the holder of the Sandoz ANDA and its affiliates the non-exclusive right to market a generic intravenous acetaminophen product in the United States under the Sandoz ANDA beginning December 6, 2020, or earlier under certain circumstances. We also agreed that in the event that we determine to launch an authorized generic version of OFIRMEV (i.e., a generic version marketed under our NDA) in the U.S. and Perrigo elects not to exercise its right of first refusal to become the distributor of the authorized generic version of the product, we will grant a similar right of first refusal to the holder of the Sandoz ANDA on substantially the same terms as those previously granted to Perrigo. In addition, the license agreement will contain provisions regarding indemnification, confidentiality and other customary provisions for agreements of these kinds. The settlement documents are subject to submission to the Federal Trade Commission and the U.S. Department of Justice. Litigation remains ongoing against Fresenius, and the bench trial for such lawsuit is tentatively scheduled to commence on July 14, 2014.

In December 2013, we received a notice from Wockhardt USA LLC, or Wockhardt, stating that Wockhardt filed an ANDA containing a Paragraph IV patent certification with the FDA for a generic version OFIRMEV. This notice stated that the Paragraph IV patent certification was made with respect to both the '222 patent and the '218 patent. We filed suit against Wockhardt Limited, Wockhardt BIO AG and Wockhardt on January 22, 2014 in the U.S. District Court of Delaware, and on January 23, 2014, in the U.S. District Court of New Jersey.

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 6, 2021 if pediatric exclusivity is granted). However, given the unpredictability inherent in litigation, we cannot predict the outcome of these matters or any other litigation.

'222 and '218 Patents: Ex Parte Reexamination

In September 2012, an unidentified third party (subsequently identified as Exela) filed with the United States Patent and Trademark Office, or USPTO, a Request for Ex Parte Reexamination of the '222 patent. In December 2012, we received notice that the USPTO had granted the Request for Reexamination. The reexamination process is provided for by law and requires the USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO. In February 2013, we and Pharmatop filed with the USPTO a patent owner's statement commenting on the reexamination request, and in April 2013, Exela filed comments in response to the patent owner's statement. In a non-final, initial office action issued by the USPTO on August 14, 2013, the USPTO rejected certain claims of the '222 patent. A response to the first office action was filed in November 2013.

In addition, in January 2014, an unidentified third party filed with the USPTO a Request for Ex Parte Reexamination of the '218 patent. All of the claims of the '222 and '218 patents remain valid and in force during the reexamination proceedings. Because we and Pharmatop believe that the scope and validity of the patent claims in these patents are appropriate and that the USPTO's prior issuances of the patents were correct, we, in conjunction with Pharmatop, will vigorously defend these patents. We cannot predict whether we and Pharmatop ultimately will succeed in maintaining the scope and validity of the claims of these patents during reexamination. If any of the patent claims in these patents ultimately are narrowed during prosecution before the USPTO, the extent of the patent coverage afforded to OFIRMEV could be impaired, which could potentially harm our business and operating results.

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'218 Patent Litigation: Exela Pharma Sciences, LLC

In April 2012, Exela filed suit against David J. Kappos and the USPTO in the United States District Court for the Eastern District of Virginia for declaratory judgment seeking a reversal of the USPTO's decision not to act on a petition by Exela to vacate the USPTO's April 2003 order reviving the international application for the '218 patent. The lawsuit followed the USPTO's rejection of Exela's petition to the USPTO filed in November 2011, which sought to vacate the April 23, 2003 order granting Pharmatop's petition to revive the '218 patent. The USPTO determined that Exela lacked standing to seek such relief. Exela also seeks declaratory judgment that the USPTO's rules and regulations that allow for revival of abandoned, international patent applications under the "unintentional" standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. Our motion to intervene in this lawsuit was granted in October 2012. In December 2012, the district court dismissed the case with prejudice as barred by the applicable statute of limitations. In February 2013, Exela appealed the district court's decision to the Court of Appeals for the Federal Circuit. The Court of Appeals heard oral argument on the appeal in February 2014. A decision by the Court of Appeals in favor of Exela could result in the invalidation of the '218 patent.

Stockholder Class-Action Litigation Regarding Our Pending Acquisition by Mallinckrodt plc

Following the February 11, 2014, announcement that we had entered into an agreement and plan of merger with Mallinckrodt and Merger Sub, six putative class-action lawsuits were filed in the Court of Chancery of the State of Delaware: *Wolfson v. Cadence Pharmaceuticals, Inc., et al.*, No. 9341-VCP (filed February 12, 2014); *Goode v. Garner, et al.*, No. 9361-VCP (filed February 18, 2014); *Bushansky v. Cadence Pharmaceuticals Inc., et al.*, No. 9365-VCP (filed February 19, 2014); *Bokol v. Cadence Pharmaceuticals Inc., et al.*, No. 9367 (filed February 19, 2014); *Elvir v. Cadence Pharmaceuticals Inc., et al.*, No. 9370-VCP (filed February 19, 2014); and *Nguyen v. Cadence Pharmaceuticals, Inc., et al.*, No. 9376-VCP (filed February 21, 2014). Two substantially identical putative class-action lawsuits were filed in the Superior Court of California, County of San Diego: *Denny v. Cadence Pharmaceuticals, Inc., et al.*, No. 37-2014-00002579-CU-BT-CTL (filed February 13, 2014) and *Militello v. Cadence Pharmaceuticals, Inc., et al.*, No. 37-00003634-CU-BT-CTL (filed February 20, 2014). The complaints allege that members of our board of directors breached their fiduciary duties to our stockholders in connection with the proposed transaction and that the merger agreement involves an unfair price, an inadequate sales process, and unreasonable deal protection devices that purportedly preclude competing offers. The complaints other than *Bushansky* further allege that we, Mallinckrodt, and/or Merger Sub aided and abetted the alleged breaches of fiduciary duties. The lawsuits seek an injunction against the consummation of the merger and rescission of the merger agreement to the extent the merger may already be consummated prior to the entry of the court's final judgment, and an award of costs and expenses, including attorneys' and experts' fees.

We intend to vigorously defend against these claims. The outcome of this litigation cannot be predicted at this time and any outcome in favor of the plaintiffs could have an adverse effect on the proposed transaction, our financial condition, and our results of operations.

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 21, 2014, there were 89,183,960 shares of common stock outstanding held by approximately 25 stockholders of record. Many stockholders hold their shares in street name and we believe that there are more than 5,500 beneficial owners of our common stock. The closing price of our common stock on the NASDAQ Global Market on December 31, 2013, the last trading day in 2013, was \$9.05 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,			
	2013		2012	
	High	Low	High	Low
First Quarter	\$ 6.85	\$4.45	\$4.37	\$3.44
Second Quarter	\$ 8.26	\$6.24	\$3.70	\$2.56
Third Quarter	\$ 8.07	\$4.96	\$4.87	\$3.49
Fourth Quarter	\$10.09	\$4.74	\$5.00	\$2.88

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2013, 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 June 2010 upon the approval of 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	10,686,905 ⁽¹⁾	\$ 6.72 ⁽²⁾	3,125,966 ⁽³⁾
Equity compensation plans not approved by security holders.	—	—	—
Total	10,686,905	\$ 6.72⁽²⁾	3,125,966⁽³⁾

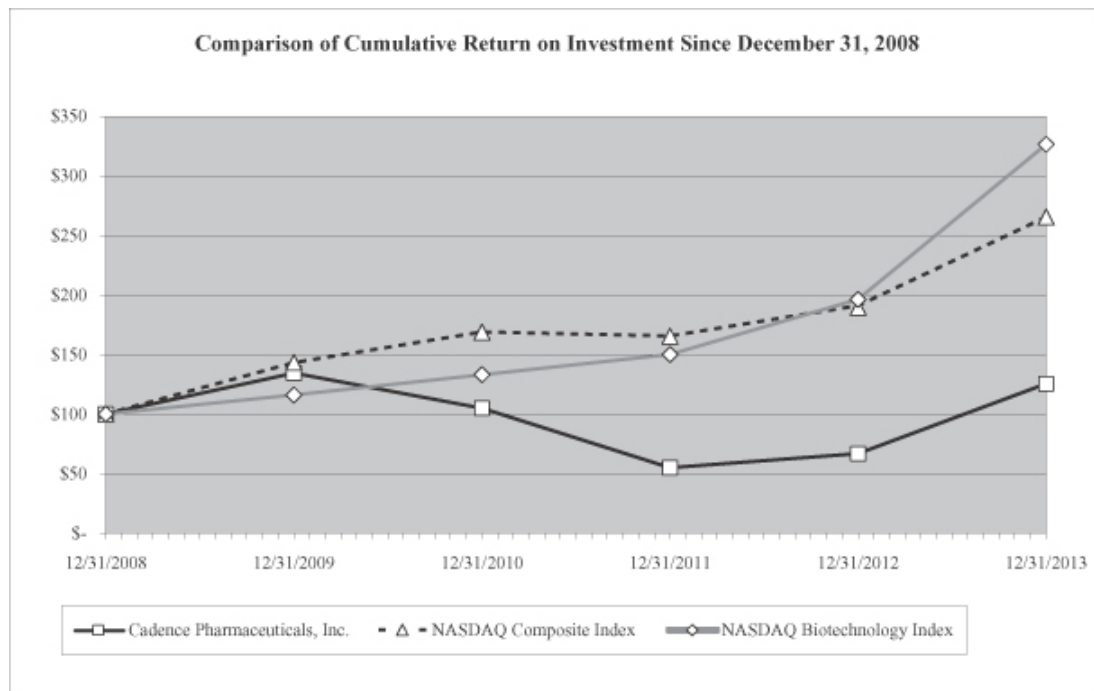
⁽¹⁾ Of these shares of common stock, 9,941,220 shares were subject to outstanding options under the 2006 Equity Incentive Award Plan and 742,685 shares were subject to outstanding options under the 2004 Equity Incentive Award Plan. In addition, 3,000 of the shares were subject to outstanding restricted 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 3,000 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, 2013, 2012, 2011, 2010, and 2009, the board of directors approved the amount of shares authorized for future issuance under the 2006 Plan to be increased by 2,570,060 shares, 3,334,952 shares, 1,893,220 shares, 1,766,960 shares and 1,269,576 shares, respectively, under this provision. Effective January 1, 2014, the board of directors authorized an additional 3,295,349 shares for future issuance under the 2006 Plan pursuant to the provision.

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 31, 2008, 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 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

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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, 2013 and 2012 and the related audited statements of operations and of cash flows for each of the three years in the period ended December 31, 2013 and notes thereto appear elsewhere in this Annual Report on Form 10-K. Audited balance sheets at December 31, 2011, 2010 and 2009 and the related audited statements of operations and of cash flows for 2010 and 2009 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 share and per share data)	Year Ended December 31,				
	2013	2012	2011	2010	2009
Statement of Operations Data:					
Product revenue, net	\$ 110,529	\$ 50,066	\$ 11,486	\$ —	\$ —
License revenue	2,027	118	5,210	—	—
Total net revenue	112,556	50,184	16,696	—	—
Cost of product sales	37,973	23,256	12,406	—	—
Amortization of patent license	1,343	1,343	1,567	—	—
Research and development	6,743	6,519	8,885	13,757	19,464
Selling, general and administrative	94,482	86,843	81,504	39,347	24,620
Impairment of long-lived assets	—	7,723	—	1,522	—
Other	(441)	1,174	1,076	291	413
Loss from operations	(27,544)	(76,674)	(88,742)	(54,917)	(44,497)
Interest income	69	123	136	106	182
Interest expense	(4,467)	(4,449)	(4,424)	(2,144)	(1,137)
Other income (expense)	7,648	27	9	312	(39)
Net loss	<u>\$ (24,294)</u>	<u>\$ (80,973)</u>	<u>\$ (93,021)</u>	<u>\$ (56,643)</u>	<u>\$ (45,491)</u>
Basic and diluted net loss per share ⁽¹⁾	<u>\$ (0.28)</u>	<u>\$ (0.95)</u>	<u>\$ (1.41)</u>	<u>\$ (1.09)</u>	<u>\$ (0.93)</u>

⁽¹⁾ There is a lack of comparability in the per share amounts between the periods presented as a result of the issuance of 21,800,000 shares of common stock pursuant to a public offering in the fourth quarter of 2011, 12,500,000 shares of common stock pursuant to a public offering in the fourth quarter of 2010 and 12,040,000 shares of common stock pursuant to a private placement in the first quarter of 2009.

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(in thousands)	As of December 31,				
	2013	2012	2011	2010	2009
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	\$ 57,401	\$ 62,072	\$ 127,227	\$ 134,141	\$ 82,006
Accounts receivable, net	\$ 9,300	\$ 6,152	\$ 2,208	\$ —	\$ —
Inventory	\$ 8,646	\$ 6,498	\$ 1,388	\$ 485	\$ —
Working capital	\$ 41,345	\$ 55,517	\$ 116,892	\$ 121,319	\$ 67,193
Total assets	\$ 90,803	\$ 97,679	\$ 163,665	\$ 163,786	\$ 92,563
Long-term debt, less current portion and discount	\$ 18,538	\$ 28,818	\$ 28,696	\$ 24,654	\$ —
Accumulated deficit	\$(471,950)	\$(447,656)	\$(366,683)	\$(273,662)	\$(217,019)
Total stockholders' equity	\$ 34,878	\$ 47,811	\$ 119,310	\$ 123,960	\$ 75,063

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 products principally for use in the hospital setting. We intend to build a leading franchise in the hospital setting, continuing to focus on differentiated products with significant unmet commercial potential that are complementary to our current product, OFIRMEV® (acetaminophen) injection, and enable us to effectively leverage our commercial infrastructure.

In 2006, we in-licensed the exclusive U.S. and Canadian rights to OFIRMEV an intravenous formulation of acetaminophen, from BMS, which currently markets the product in Europe and several other markets under the brand name Perfalgan®. In November 2010, OFIRMEV was approved by the FDA, and we commercially launched OFIRMEV in the U.S. in January 2011. Our initial focus during the launch of OFIRMEV was to ensure formulary adoption, which we believe was an important first step to broad market acceptance, and by the end of 2013, OFIRMEV had been successfully placed on formulary at approximately 2,400 institutions. Our current focus is educating doctors, pharmacists and other healthcare professionals on the appropriate use of OFIRMEV and effective approaches to utilizing multimodal analgesia. We believe we are beginning to see the dividends of this strategy as our revenue has consistently grown each quarter since launch. For example, during the year ended December 31, 2013, we recorded net product revenue of \$110.5 million, an increase of \$60.4 million, or 121%, from the \$50.1 million reported for 2012.

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, 2013, we have received total net proceeds of approximately \$448.4 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Additionally, we have entered into 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, 2013, the principal balance outstanding on our current facility with this loan syndicate was \$30.0 million.

Recent Development

On February 10, 2014, we entered into the Merger Agreement with Mallinckrodt and Merger Sub pursuant to which, and on the terms and subject to the conditions in the Merger Agreement, among other things, Merger Sub commenced a tender offer on February 19, 2014 to acquire all of the outstanding shares of our common stock at a purchase price of \$14.00 per share in cash, without interest. The Merger Agreement includes a remedy of specific performance and is not subject to a financing condition.

The obligation of Merger Sub to purchase the shares of our common stock validly tendered pursuant to the tender offer is subject to the satisfaction or waiver of a number of conditions set forth in the Merger Agreement, including (1) that there shall have been validly tendered and not validly withdrawn a number of shares of our common stock that, when added to the shares then owned by Mallinckrodt and its subsidiaries, represents one more than 50% of the total number of shares of our common stock outstanding at the time of the expiration of the

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tender offer, (2) the expiration or termination of applicable waiting periods under the HSR Act, (3) the accuracy of the representations and warranties and compliance with covenants contained in the Merger Agreement, (4) the absence of any law, order, injunction or decree by any government, court or governmental entity that would make illegal or otherwise prohibit the tender offer or the merger, (5) there not having been a material adverse effect with respect to our company, (6) the delivery of certain audited and unaudited financial statements, and (7) other customary conditions.

The Merger Agreement contains certain termination rights in favor of each our company and Mallinckrodt, including under certain circumstances, the requirement for us to pay to Mallinckrodt a termination fee of approximately \$20.2 million, or approximately 1.5% of the purchase price. We also agreed (1) to cease any existing, and agreed not to solicit or initiate any additional, discussions with third parties regarding other proposals to acquire us and (2) to certain restrictions on our ability to respond to such proposals, subject to fulfillment of certain fiduciary requirements of our board of directors.

Following the completion of the tender offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into us, with our company surviving as an indirect wholly owned subsidiary of Mallinckrodt, pursuant to the procedure provided for under Section 251(h) of the Delaware General Corporation Law without any stockholder approvals. At the Effective Time, by virtue of the merger and without any action on the part of the holders of any shares of our common stock, each outstanding share of our common stock, other than any shares owned by Mallinckrodt, Merger Sub or any wholly owned subsidiary of Mallinckrodt or held in our treasury, or any stockholders who are entitled to and who properly exercise appraisal rights under Delaware law, will be canceled and converted into the right to receive an amount in cash equal to the Offer Price. In addition, (1) effective as of immediately prior to the Effective Time, each of our outstanding stock options will fully vest and automatically be canceled and terminated as of the Effective Time and the holder thereof will be entitled to receive an amount in cash, without interest and less the amount of any tax withholding, equal to the product of (a) the number of shares of our common stock underlying such option multiplied by (b) the excess, if any, of the Offer Price over the exercise price per share of such option, (2) effective as of immediately prior to the Effective Time, each of our outstanding restricted stock units, other than the Specified Restricted Stock Units, will fully vest and the restrictions thereon will lapse, and each such restricted stock unit will be canceled and converted into the right to receive an amount in cash, without interest and less the amount of any tax withholding, equal to the product of (a) the Offer Price multiplied by (b) the number of shares of our common stock underlying such restricted stock unit, and (3) at the Effective Time, each outstanding Specified Restricted Stock Unit will be canceled and converted into an award, or a Converted Award, representing the right to receive an amount in cash equal to the product of (a) the Offer Price multiplied by (b) the number of shares of our common stock underlying such Specified Restricted Stock Unit. Each Converted Award shall continue to vest and be settled in cash in accordance with the terms of the applicable Specified Restricted Stock Unit award agreement, subject to accelerated vesting under certain circumstances, including in the event of the holder's death or disability or an involuntary termination of employment that would otherwise qualify the holder to severance under any employment or severance plan or agreement to which the holder is a party or in which the holder is eligible to participate as of the date of grant. The foregoing treatment of the Specified Restricted Stock Unit Awards will supersede any more favorable vesting provisions in our equity plan or any employment or severance plan or agreement to which the holder is a party or in which the holder is eligible to participate (including employment agreements with our executive officers).

The Merger Agreement contains customary representations, warranties and covenants, including covenants obligating us to continue to conduct our business in the ordinary course and to cooperate in seeking regulatory approvals.

Our board of directors has unanimously (1) determined that the Merger Agreement and the transactions contemplated thereby are advisable and fair to, and in the best interests of, our stockholders, (2) approved and declared advisable the Merger Agreement and the transactions contemplated thereby and (3) resolved to

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recommend acceptance of the tender offer by our stockholders. The board of directors of Mallinckrodt has also unanimously approved the transaction. We expect to complete the Merger in mid to late March 2014, subject to the satisfaction of the closing conditions.

Operations

Revenue

Our primary source of revenue is from the sale of OFIRMEV to hospitals and other end-user customers. Additionally, we have licensed certain data to Terumo Corporation, or Terumo, for their use in seeking and obtaining regulatory approval and commercializing the same intravenous formulation of acetaminophen in Japan.

Product Revenue

In January 2011, we launched commercial sales of OFIRMEV and began shipping product to independent wholesalers, which sell OFIRMEV to hospitals and other end-user customers. Our initial focus for revenue growth was to promote rapid hospital formulary adoption of the product. During the second half of 2011, our sales force placed additional emphasis on generating pull-through hospital sales of OFIRMEV, and we have continued this focus by actively promoting the product through a variety of marketing programs to inform end-user customers about OFIRMEV. Our goal is that these programs will lead to an increasing number of patients being treated with OFIRMEV, which, in turn, will lead to increased utilization of OFIRMEV. We believe these efforts have had a positive impact on our growth as unique accounts that had ordered OFIRMEV as of December 31, 2013, grew 30% to more than 4,900, from over 3,750 at December 31, 2012. Further, the average order frequency of our end-user customers increased by approximately 16% during the year ended December 31, 2013, compared to 2012, and the average order size of our end-user customers increased by 23% during the same period.

The impact of the continued growth in these metrics is evident in our net product revenue trends. Specifically, our net product revenue for the year ended December 31, 2013, was \$110.5 million, 121% higher than the \$50.1 million reported for the year ended December 31, 2012, and more than nine times the \$11.5 million reported for the year ended December 31, 2011. Included in net revenue for the year ended December 31, 2013, was \$2.6 million of net revenue recognized during the period on shipments of product that had previously been deferred as a result of a change in our accounting estimate for revenue recognition.

We intend to continue our marketing strategies to promote OFIRMEV for the foreseeable future and believe there are substantial growth opportunities available through continued promotion of the product.

License Revenue

In November 2010, we entered into a data license agreement with 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, under the agreement we were to provide to Terumo, without charge, up to 500 hours of technical assistance and consulting services through November 2012 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 and 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 was recognized during the year ended December 31, 2012, upon the expiration of our obligation to provide up to 500 hours of technical assistance and consulting services.

In June 2013, Terumo received regulatory approval from the Japanese Ministry of Health, Labour & Welfare for the IV acetaminophen formulation licensed from us and Pharmatop, and in November 2013,

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Terumo commenced commercial sales of its product. Pursuant to the terms of the data license agreement, we received from Terumo a non-refundable payment of \$2.0 million which we recorded as licensing revenue during the year ended December 31, 2013. In addition, we are entitled to royalty payments on the product's commercial sales in Japan, which we will recognize as royalty revenue in the quarter in which we receive the sales information from Terumo. We did not recognize any royalty revenue during the years ended December 31, 2013, 2012 and 2011, and we do not expect this royalty revenue to contribute materially to our financial results in the foreseeable future.

Cost of Sales

Our cost of sales consists primarily of third-party manufacturing fees paid to suppliers, in addition to freight, indirect costs, and personnel overhead costs. 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. The cost of sales we report for the quarterly and annual periods are primarily driven by sales volume, however, they are also impacted by production volumes of our product, manufacturing price variances, variances in freight costs, variances of our overhead costs and any inventory adjustment charges we may record.

The finished product, OFIRMEV, is currently supplied to us by BMS Anagni. Previously, Baxter Healthcare Corporation, or Baxter, also manufactured OFIRMEV for us. However, in February 2012, we temporarily suspended production of OFIRMEV by Baxter and in March 2013, we and Baxter, mutually agreed to terminate our supply agreement for OFIRMEV. We continued to incur certain manufacturing costs related to Baxter during the suspension, which are included in cost of sales for the year ended December 31, 2012. In February 2012, we placed certain inventory produced by Baxter on indefinite hold as a result of our February 2012 voluntary recall of product manufactured by Baxter and recorded the write-off of this inventory in costs of sales. In addition, at December 31, 2012, we accrued for the estimated destruction costs related to this product. Moreover, due to the termination of the supply agreement with Baxter, we reduced the carrying value of our manufacturing assets and manufacturing equipment and facility construction assets in process to their current estimated fair value as of December 31, 2012. Further, as of December 31, 2012, we fully impaired our estimated asset retirement obligation associated with the supply agreement because of our obligation to remove our equipment. See Critical Accounting Policies and Estimates — Long-Lived Assets for further discussion of this impairment.

During the 2012 suspension of production by Baxter, we transitioned our supply of OFIRMEV to BMS Anagni, which is presently acting as our sole supplier for the product. As a result of this transition, and in an effort to minimize any potential short-term supply disruption, we incurred expedited freight costs on certain shipments of OFIRMEV during the first half of 2012. These expedited freight costs were recognized through the sale of the related inventory in 2012 and there was no impact from these shipments on our costs of sales in 2013. No further supply shortages are anticipated as a result of the termination of the Baxter agreement, as we continue to distribute product manufactured by BMS Anagni.

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. However, as these payments are dependent upon future levels of net sales, we are unable to estimate with any certainty the timing of when these charges may be incurred.

Research and Development Expenses

Our research and development expenses relate predominantly to the development of product candidates, including OFIRMEV, and the ongoing regulatory compliance requirements for our commercialized products. Historically, 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 have since reduced our research and development expenses. However, we expect to continue to incur research and development expenses related to OFIRMEV in future periods, although it is difficult to anticipate the scope and magnitude of our future research and development expenses. For example, we continue to incur costs in maintaining our regulatory compliance, and in the third quarter of 2012, we began enrolling patients in an ongoing FDA-required post-approval clinical trial for OFIRMEV in pediatric patients under two years of age. We may also conduct additional 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 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 increased significantly following the approval of OFIRMEV in November 2010 as we hired our sales force and related personnel to support the commercial efforts for OFIRMEV and we continue to incur these costs. Further, we began to incur additional legal costs in 2012 related to our intellectual property litigation and we continue to incur these costs as we enforce our intellectual property rights. We expect to continue to incur significant selling, general and administrative expenses as we execute our marketing and sales strategies for OFIRMEV, enforce our intellectual property rights and operate our business. However, we are unable to estimate with any certainty the level of selling, general and administrative expenses we will incur in supporting OFIRMEV or any other product or product candidate we may acquire or in-license in the future.

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 the related debt issuance costs. Other income and expense includes gains or losses recognized on transactions denominated in foreign currencies and other transactions not related to our operations, including the waiver and termination of our option to purchase Incline Therapeutics, Inc., or Incline, and the sale of our Incline stock in January 2013.

Our current loan and security agreement had a principal balance of \$30.0 million throughout 2013 as we made interest-only payments under the agreement. However, in January 2014, we began making equal monthly principal and interest payments to fully amortize the balance over a 30-month term. This facility has a fixed interest rate of 10.9545% and, as we make principal payments, we anticipate that our interest expense will decline.

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, 2013, we had federal and state net operating loss carryforwards of approximately \$392.1 million and \$387.6 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2014 for state purposes. Additionally, we had both federal and state research and development tax credit carryforwards of approximately \$4.1 million and \$2.5 million, respectively. The federal tax credits will begin expiring in 2025 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 recently completed an analysis that examined our ownership changes through December 31, 2012, pursuant to Sections 382 and 383 and determined that we experienced an ownership change in March 2006. However, this ownership change did not result in the forfeiture of any net operating losses or research and development credits. 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. There is risk that additional changes in ownership have occurred since the completion of our analysis, which was through December 31, 2012. If a change in ownership were to have occurred, additional net operating loss and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S., or GAAP, requires us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Some of our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. The following accounting policies involve critical accounting estimates because they are particularly dependent on estimates and assumptions made by management about matters that are highly uncertain at the time the accounting estimates are made. In addition, while we have used our best estimates based on facts and circumstances available to us at the time, different estimates reasonably could have been used. Changes in the accounting estimates we use are reasonably likely to occur from time to time, which may have a material impact on the presentation of our financial condition and results of operations.

Our most critical accounting estimates include 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 predominantly to wholesalers. Our primary distribution channel for OFIRMEV involves our third party logistics distributor, which distributes the product to independent wholesalers, which in turn distribute the product directly to hospitals and other end-user customers. We also sell the product directly to end-user customers, and we have contracted with group purchasing organizations whose members consist of hospitals and other-end user customers.

Our wholesaler agreements provide selling prices that are fixed on the date of sale, although we offer discounts to certain group purchasing organizations, end-user hospitals and government 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.

OFIRMEV, which was launched in January 2011, is our first and only commercially available product. Because we initially had limited product return data, we deferred the recognition of revenue on sales to wholesalers and, instead, recognized revenue at the time that product was sold by a wholesaler to an end-user customer. Shipments of product that were not recognized as revenue were treated as deferred revenue. However, as of January 1, 2013, we determined that we had obtained sufficient product return history to reasonably estimate future wholesaler returns. Since that time, we have recognized revenue at the time product is sold to a wholesaler consistent with other companies with products at this stage of commercialization. As a result of this change, we recorded a one-time adjustment in January 2013 to recognize revenue that had previously been deferred, resulting in additional net revenue of \$2.6 million and cost of sales of \$0.9 million during the period.

We record certain fees, sales reserves and allowances as a reduction to gross revenue, as applicable. These reserves and allowances include distribution service fees, a prompt payment reserve, a group purchasing discount and administrative service fee, discounts to certain end-user hospitals and governmental programs, and a reserve for estimated product returns, 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. 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 organization administrative fee that we incur in exchange for administrative services provided by the group purchasing organizations for these transactions is also accrued at the time of sale. We also provide predetermined discounts under certain government programs, which are recorded at the time of sale. Our product return estimate is based on historical return rates of our product.

Revenue from the data and services elements of our data license agreement with Terumo was 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 of 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

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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 was recognized as revenue as such services were rendered, through termination of the required service period in November 2012.

In addition to the data and services revenue previously recognized, the data license agreement with Terumo also entitled us to receive a one-time, non-refundable license fee upon Terumo's first commercial sale of its IV acetaminophen product in Japan, which occurred in November 2013, and royalty payments on any commercial sale of the product in Japan. We have determined these payments to be contingent fees in accordance with multiple-element arrangement guidance and we recognize the related revenue as it is earned in accordance with the terms of the agreement. Accordingly, we recognized \$2.0 million of license revenue in November 2013 for the one-time license fee paid by Terumo following the first commercial sale of its IV acetaminophen product. We recognize royalty revenue on Terumo's sales at the time we can reliably estimate such amount. We did not recognize any royalty revenue during the year ended December 31, 2013, as we could not accurately estimate the total sales by Terumo during the period. We anticipate we will record these quarterly royalties one quarter in arrears as Terumo submits its sales and related data to us, the amount of which is not expected to be material.

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, indirect and personnel overhead costs, freight-in, and, if applicable, internal manufacturing overhead, and other direct costs, if any. 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.

In February 2012, we placed certain inventory produced by Baxter on indefinite hold and temporarily suspended production of OFIRMEV by Baxter pending the outcome of an investigation into unidentified particulate matter observed during routine product stability testing. In March 2013, we and Baxter mutually agreed to terminate our supply agreement for OFIRMEV. We recorded charges of \$5.6 million for the fourth quarter of 2011 and \$0.2 million for the first quarter of 2012 in cost of sales to fully write-down the value of this inventory. Further, we accrued for the destruction costs related to this product as of December 31, 2012. During the suspension, we transitioned the supply of OFIRMEV to BMS Anagni, which is presently acting as our sole supplier for the product. No supply shortages are anticipated as a result of the termination of our supply agreement with Baxter as we continue to distribute product manufactured by BMS Anagni.

Stock-Based Compensation

We account for stock-based compensation by calculating the fair value of equity awards on the date of grant. 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 value 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

We evaluate our 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 and planned use 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.

A substantial portion of our capital assets are associated with our previous supply agreement with Baxter. As part of the agreement, which was terminated in March 2013, we agreed to fund specified improvements to the facilities and the construction of the manufacturing equipment to be used for the production of OFIRMEV. In February 2012, we suspended production of OFIRMEV by Baxter, and in March 2013, we and Baxter mutually terminated our supply agreement for OFIRMEV. As a result of the termination, we reduced the carrying value of our manufacturing assets, manufacturing equipment and facility construction assets in process to their current estimated fair value, resulting in an impairment charge of \$7.0 million for the year ended December 31, 2012. Moreover, we estimated the value of the retirement obligation associated with the supply agreement and fully impaired the asset, resulting in a charge of \$0.7 million as of December 31, 2012. In June 2013, we removed our equipment from Baxter's facility and transferred it to alternative locations as we seek appropriate buyers, alternative uses or other disposal methods for the equipment. We completed our asset retirement obligation associated with the supply agreement in 2013 and released the balance of the accrued obligation, which resulted in a gain of \$0.1 million that was recorded in other operating expenses.

The carrying value on our balance sheet of the manufacturing equipment at December 31, 2013 and 2012 was \$0.9 million and \$1.0 million, respectively. The carrying value of the construction-in process assets related to the agreement at December 31, 2013 and 2012 was \$0.3 million and \$0.4 million, respectively. The balance of the accrued asset retirement obligation, included in accrued liabilities, at December 31, 2012, was \$0.7 million. There was no similar liability for the asset retirement obligation at December 31, 2013.

Results of Operations

Years ended December 31, 2013 and 2012

Revenue

Net product revenue from the sale of OFIRMEV was \$110.5 million during the year ended December 31, 2013, an increase of \$60.4 million, or 121%, from the \$50.1 million reported for the year ended December 31, 2012. Additionally, we recognized \$2.0 million of license revenue during 2013 under our data license agreement with Terumo and Pharmatop following Terumo's first commercial sale of its IV acetaminophen product in Japan. In 2012, we recognized \$0.1 million for services we provided to Terumo under the data license agreement.

The increase in product revenue during 2013 as compared to 2012 was primarily due to the increased utilization of OFIRMEV in a variety of surgical settings and price increases we implemented during 2012 and 2013. The increase in utilization is demonstrated by increases in the average order size and frequency of orders by end-user customers. For example, the average order size for our product by end-user customers increased by 23% in 2013 as compared to 2012. Further, the average reorder rate by our end-user customers increased by approximately 16% in 2013 as compared to 2012.

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The price increases implemented with respect to OFIRMEV resulted in a higher average selling price during 2013 as compared to 2012. The impact of these price increases resulted in additional net revenue of approximately \$13.2 million in 2013 as compared to 2012.

Costs and Expenses

Cost of Product Sales. Our cost of product sales for the year ended December 31, 2013, was \$38.0 million, or 34% of net product revenue, compared to \$23.3 million, or 47% of net product revenue, for the comparable period in 2012. The improvement in our costs of product sales as a percentage of net product revenue in 2013 was primarily due to costs incurred during 2012 related to our suspension of production at the Baxter facility that were not incurred during 2013. More specifically, we incurred expedited freight costs on certain shipments of OFIRMEV from BMS Anagni in order to meet demand for OFIRMEV following the suspension of manufacturing at Baxter's facility in February 2012. Additionally, during 2012, we sustained unabsorbed manufacturing costs during the suspension of production by Baxter, which were recognized as period expenses during the year. Similar expedited freight and unabsorbed manufacturing costs were not incurred during 2013. Also contributing to the improvement in our cost of sales as a percentage of net product revenue was the increase in our average selling price combined with a lower average supply price for product sold in 2013 compared to 2012, a lower overhead cost allocation driven by increased production volumes and lower in-bound freight costs from more favorable terms.

Patent Amortization. Patent amortization for each of the years ended December 31, 2013 and 2012 was \$1.3 million, as we continue to amortize the \$15.0 million license payment made to BMS in November 2010 following the approval of our NDA for OFIRMEV over the estimated life of the patent. As of December 31, 2013, the unamortized balance of our license payment was \$10.7 million.

Research and Development Expenses. Research and development expenses increased \$0.2 million for the year ended December 31, 2013, to \$6.7 million, compared to \$6.5 million for 2012. This increase was primarily due to additional costs incurred in 2013 associated with our ongoing pediatric clinical trial, mostly offset by lower personnel costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased \$7.7 million, or 9%, for the year ended December 31, 2013, to \$94.5 million, compared to \$86.8 million for 2012. This increase was mostly attributable to higher legal expenses incurred during 2013 related to our intellectual property litigation. We also incurred higher costs in 2013 related to corporate development activities as compared to 2012.

Impairment of Long-Lived Assets. During the year ended December 31, 2012, we recorded impairment charges totaling \$7.0 million to reduce the value of our manufacturing assets at Baxter to their estimated net realizable value. The production of OFIRMEV at Baxter had been suspended since February 2012, and in March 2013, we and Baxter mutually agreed to terminate our supply agreement. In addition, we impaired the estimated asset retirement obligation associated with the terminated supply agreement as of December 31, 2012, resulting in a charge of \$0.7 million for the year ended December 31, 2012. No similar impairment charges were recorded during the year ended December 31, 2013. However, during 2013, we completed our asset retirement obligations associated with the supply agreement and released the balance of the accrued obligation, resulting in a gain of \$0.1 million, which was recorded in other operating expenses.

Other Expenses. During the year ended December 31, 2013, we recognized a gain of \$0.6 million from an insurance claim on damaged product. Additionally, we completed our asset retirement obligations associated with the Baxter supply agreement and released the balance of the accrued obligation related to these assets, resulting in a gain of \$0.1 million. Partially offsetting these gains in 2013 was a loss on disposal of an asset of \$0.2 million.

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During 2012, we recorded a loss of \$0.9 million upon the disposal of a manufacturing asset being constructed and accrued for the anticipated destruction costs related to recalled inventory which had been written-off during 2012, resulting in a charge of \$0.3 million.

Other Income and Expenses, Net

Other income for the year ended December 31, 2013, was \$3.3 million, representing an increase of \$7.6 million from the net expense of \$4.3 million incurred for 2012. This increase was primarily related to the waiver and termination of our option to purchase Incline and the sale of our Incline stock in January 2013. We recorded these assets using the cost method with a combined value of \$7.0 million, and as a result of the transaction whereby we received \$14.7 million, recorded a gain of \$7.7 million during 2013. No similar gain was recorded during the year ended December 31, 2012.

Our interest expense for the year ended December 31, 2013, was \$4.5 million, which was consistent with 2012 as the outstanding principal balance under our credit facility remained constant throughout 2012 and 2013. However, in January 2014, we began making equal monthly principal and interest payments to fully amortize the balance over a 30-month term. This facility has a fixed, stated interest rate of 10.9545% and, as we make principal payments, we anticipate that our interest expense will decline.

Years ended December 31, 2012 and 2011

Revenue

During the year ended December 31, 2012, we recognized \$50.1 million of net product revenue from the sale of OFIRMEV to hospitals and other end-users, an increase of \$38.6 million, or 336%, from the \$11.5 million reported for the year ended December 31, 2011. 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 a data license agreement. During 2012, we recognized \$0.1 million for the remaining consulting hours required under the agreement.

The increase in product revenue during 2012 as compared to 2011, our initial launch year for OFIRMEV, was primarily due to the continued expansion of our end-user customer base and the penetration of their use of OFIRMEV in a variety of surgical settings. For example, unique end-user accounts increased from approximately 2,200 at December 31, 2011 to over 3,750 at December 31, 2012. Further, this increasingly broad customer base has increased the frequency at which they are ordering the product, as well as their average order size. For example, the average order size for end-user customers for the fourth quarter of 2012 increased more than 40%, as compared to the average order size for the fourth quarter of 2011. Moreover, the frequency with which these customers ordered the product increased by 16% in the fourth quarter of 2012 compared to the fourth quarter of 2011. In addition, we implemented a price increase during 2012, which resulted in our average net selling price for 2012 increasing 3% from the average net selling price for 2011.

Costs and Expenses

Cost of Product Sales. Our cost of product sales for the year ended December 31, 2012, was \$23.3 million, or 47% of net product revenue, compared to \$12.4 million, or 108% of net product revenue, for the comparable period in 2011. The improvement in our costs of sales as a percentage of net product revenue in 2012 was primarily due to a reduction in inventory losses we recorded during the 2012 period as compared to 2011. For example, we recorded a \$5.6 million charge in 2011 for inventory losses, compared to a similar charge of \$0.2 million in 2012. These losses relate to inventory that was placed on indefinite hold due to the investigation into the cause of unidentified particulate matter observed in the product during routine product stability testing at Baxter's manufacturing facility.

Additional improvements in our cost of sales as a percentage of net product revenue for 2012 include economies of scale we realized on increased sales volume during the 2012 period. However, these efficiencies

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realized in 2012 were partially offset by higher freight costs related to a supply disruption during the first quarter of the year and unabsorbed manufacturing costs we incurred on our idle manufacturing site. These excess costs were mostly related to our suspension of production by Baxter in connection with the aforementioned investigation. More specifically, we incurred expedited freight costs on certain shipments of OFIRMEV from BMS Anagni in order to meet demand for OFIRMEV following the suspension of manufacturing at Baxter's facility in February 2012. Additionally, we continued to incur certain fixed manufacturing costs at the Baxter manufacturing facility during 2012, which were recognized as a cost of product sales during the period in which they were incurred.

Patent Amortization. For the year ended December 31, 2012, we incurred \$1.3 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. For the year ended December 31, 2011, we incurred \$1.6 million of patent amortization expense.

Research and Development Expenses. Research and development expenses decreased \$2.4 million for the year ended December 31, 2012, to \$6.5 million, compared to \$8.9 million for 2011. This decrease was primarily due to our transition to a commercially-focused organization whereby we implemented a restructuring of our workforce in November 2011, resulting in the reduction of twelve employees in our research and development organization. As a result, our personnel-related costs and the corporate overhead cost allocations which are based on headcount, decreased significantly in 2012 as compared to 2011. However, in 2012 we began establishing sites and enrolling patients in our FDA-required post-approval clinical trial for OFIRMEV in pediatric patients under two years of age and began to incur costs for this trial in 2012.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased \$5.3 million, or 6.5%, for the year ended December 31, 2012, to \$86.8 million, compared to \$81.5 million for 2011. This increase was mostly attributable to higher legal expenses incurred during 2012 related to our intellectual property litigation and increased commissions earned by our hospital sales force, which was partially offset by reductions in other personnel-related costs.

Impairment of Long-Lived Assets. As of December 31, 2012, we recorded impairment charges totaling \$7.0 million to reduce the value of our manufacturing assets at Baxter to their estimated net realizable value. The production of OFIRMEV at Baxter had been suspended since February 2012, and in March 2013, we and Baxter mutually agreed to terminate our supply agreement. In addition, we impaired the anticipated asset retirement obligation associated with the terminated supply agreement as of December 31, 2012, pursuant to the terms of the terminated supply agreement and the Settlement and Termination Agreement, resulting in a charge of \$0.7 million for the year ended December 31, 2012. No similar impairment charges were recorded during the year ended December 31, 2011.

Other Expenses. In December 2012, we recorded a loss of \$0.9 million upon the disposal of a manufacturing asset being constructed. Further, we accrued for the anticipated destruction costs for the recalled inventory we wrote-off during the year, resulting in a charge of \$0.3 million for the year ended December 31, 2012. During the year ended December 31, 2011, we recorded one-time employee termination costs of \$1.1 million as part of the restructuring of our workforce in November 2011. The restructuring was due to our transition to a commercially-focused organization, which resulted in a reduction to our research and development expenses for 2012.

Other Income and Expenses, Net

Net other expense for the year ended December 31, 2012, was \$4.3 million, which was consistent with 2011. Moreover, our interest expense of \$4.4 million for 2012 was consistent with our interest expense for 2011 as the outstanding principal balance on our debt remained at \$30.0 million throughout 2012. In December 2012, we amended and restated our existing loan facility whereby we delayed the commencement of principal payments by

one year, from January 1, 2013 to January 1, 2014. The 2012 amendment did not provide for additional capital, but the stated interest rate was reduced from 10.99% to 10.9545%. As part of the 2012 amendment, we issued warrants to purchase an aggregate of 154,638 shares of our common stock at an exercise price of \$3.88 per share and made a term loan final payment in December 2012 in accordance with the terms of the prior facility, which we had been accruing during the term of the facility. We are obligated to pay a similar final payment in accordance with the terms of the 2012 amendment. Our effective interest rate under the 2012 amendment is 15.30%.

Liquidity and Capital Resources

As a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting, we enter into agreements to acquire commercial products and the right to develop and commercialize product candidates, which requires a significant amount of resources. Further, these agreements and related development programs may not result in commercially successful products that generate significant revenue and, for product candidates, even if a commercial product is developed, it could take a substantial amount of time to recover the investment in the program, if at all. 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 in addition to royalties on the net sales of OFIRMEV. Further, in developing OFIRMEV, we have incurred over \$49.1 million in research and development costs through December 31, 2013, specific to the product. However, 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, we have yet to recover our investment in the drug product and development program. For example, as of December 31, 2013, we had realized approximately \$98.4 million in gross profit on sales of OFIRMEV and we continued to operate at a loss.

OFIRMEV is currently our only product and we have no ongoing development programs for other product candidates and if we acquire, in-license or develop other drug products or drug candidates, it will likely require substantial capital resources. We previously entered into an option agreement with Incline whereby we had the option to acquire Incline. However, in December 2012, we entered into a waiver agreement with Incline pursuant to which we agreed to the buy-out and termination of that option. In January 2013, under the terms of the waiver agreement, we relinquished our option for consideration of \$13.1 million in cash. Additionally, we received \$1.5 million for the shares of Incline stock we sold as part of the transaction.

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, 2013, we have received net proceeds of approximately \$448.4 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Through December 31, 2013, the sales of shares of our preferred stock, common stock and warrants were as follows:

- from July 2004 to December 2013 (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 4,140,836 shares of common stock to our founders, employees, directors and consultants for aggregate net proceeds of \$7.4 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;

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- 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, of which 5,429,004 remain outstanding at December 31, 2013;
- 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, 2013, the current secured credit facility with this syndicate had an outstanding principal balance of \$30.0 million and we had no further available credit. Through December 31, 2013, we were making interest-only payments on the outstanding balance of this facility. In January 2014, we began 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, 2013, 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, 158,311 common shares at \$3.79 per share and 154,638 common shares at \$3.88 per share, remained outstanding from our loan agreements as of December 31, 2013.

Liquidity

As of December 31, 2013, we had \$55.1 million in cash and cash equivalents, compared to \$58.3 million at December 31, 2012. This \$3.2 million decrease in our cash and cash equivalent balance during 2013 was primarily due to the \$23.2 million of cash used in operations, partially offset by the \$14.7 million we received for the waiver and termination of our option to acquire Incline and the sale of our Incline stock. We also received a \$2.0 million license fee from Terumo following the first commercial sale of its IV acetaminophen product in Japan, \$4.3 million from the exercise of stock options and \$1.4 million from the maturity of marketable securities.

Our use of cash in operations of \$23.2 million during 2013 was \$41.1 million less than the \$64.3 million we used during 2012. This reduction was mostly due to the increase in our revenue and improved gross margin during 2013. For example, we realized gross profit of \$72.6 million in 2013 on the sale of OFIRMEV, an increase of \$45.8 million from our gross profit of \$26.8 million on the sale of OFIRMEV in 2012. However, the impact of our increased profit in 2013 was partially offset by an increase in our operating expenses, primarily related to our intellectual property litigation, and an increase in our working capital requirements. More specifically, our accounts receivable balance increased \$3.1 million during 2013 to \$9.3 million, from \$6.2 million at December 31, 2012, as a result of our increased sales. However, our accounts receivable collection period at December 31, 2013, remained relatively constant at approximately 30 days, based on our calculation of days sales outstanding.

Our net property and equipment balance at December 31, 2013, increased \$0.1 million to \$2.1 million from \$2.0 million as of December 31, 2012. This increase was mostly due to the purchase of new computer equipment and software, partially offset by depreciation and the sale of certain manufacturing equipment that had previously been located at Baxter's manufacturing facilities.

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We made no principal payments under our credit facility during 2013 and our outstanding principal balance remained at \$30.0 million as of December 31, 2013. We began making equal monthly principal and interest payments in January 2014 to fully amortize the balance over the remaining 30-month term. Under the credit facility, we are required to maintain minimum quarterly product revenue of \$12.5 million and we are subject to various other financial and non-financial covenants. We believe we were in compliance with all such covenants as of December 31, 2013.

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. However, in January 2013, we consummated our waiver agreement with Incline whereby we received aggregate proceeds of \$14.7 million as consideration for relinquishing our option to acquire Incline and sale of the 500,000 shares of Incline Series A preferred stock we held. In addition, during the fourth quarter of 2013, we received a one-time license fee of \$2.0 million related to Terumo's initial commercial sale of its IV acetaminophen product in Japan.

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;
- the level of underlying hospital demand for OFIRMEV and wholesalers' buying patterns;
- 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 arrangements;
- 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;
- our ability to successfully defend the patents for OFIRMEV and maintain our market exclusivity;
- our ability to successfully procure sufficient quantities of OFIRMEV and maintain adequate supply levels;
- regulatory developments affecting OFIRMEV or the products or product candidates of our competitors;
- costs associated with any product recalls or investigations into quality concerns; and
- variations in the level of expenses related to our development programs for any future product candidates and any further development costs associated with OFIRMEV, including our ongoing pediatric clinical trial.

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. Additional 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, which may limit our ability to timely replace maturing liabilities and to access the

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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

In operating our business, we enter into contracts and agreements that require capital resources to be consumed in future periods. The following table summarizes our scheduled contractual obligations and commitments that will affect our future liquidity as of December 31, 2013 (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	\$ 36,230	\$13,772	\$22,458	\$ —	\$ —
Third-party manufacturing obligations ⁽¹⁾	79,050	16,050	31,500	31,500	—
Operating leases ⁽²⁾	5,214	600	2,036	2,117	461
Other purchase obligations ⁽³⁾	2,314	1,362	878	74	—
License obligations ⁽⁴⁾	—	—	—	—	—
Total ⁽⁵⁾	<u>\$122,808</u>	<u>\$31,784</u>	<u>\$56,872</u>	<u>\$33,691</u>	<u>\$ 461</u>

⁽¹⁾ 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 our supply agreement with Lawrence Laboratories; however, the ultimate liability for these obligations may be reduced if our supplier fails or declines to supply a sufficient quantity of OFIRMEV in accordance with our purchase orders. The amounts presented do not include obligations under our previous supply agreement with Baxter as this agreement was terminated in March 2013. Further, the amounts presented do not include obligations under our Manufacturing and Supply Agreement with Laboratorios Grifols, S.A., as the initial contract year does not commence until the FDA has approved the product and manufacturing at this facility, and would not commence if such approval was not received.

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

⁽³⁾ Includes purchase commitments for capital expenditures and other purchase obligations for services at fixed minimum costs.

⁽⁴⁾ 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.

⁽⁵⁾ 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.

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Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2013.

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

As of December 31, 2013, our cash equivalents and short-term investment holdings consisted of investments in money market funds, debt obligations of municipalities, 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 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 cash, cash equivalents and investment securities are held at fair value. The following table shows the fair value of our cash equivalents and investment securities as of December 31, 2013 (in thousands):

	<u>Amortized Cost Basis</u>	<u>Fair Value</u>
Cash equivalents	\$ 48,975	\$ 48,975
Available-for-sale marketable securities	\$ 2,326	\$ 2,326

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 outstanding principal balance of the loan and security agreement at December 31, 2013, was \$30.0 million, and is collateralized by substantially all of our assets (excluding intellectual property). Under the terms of our current agreement, we must maintain minimum quarterly product revenue of at least \$12.5 million, are precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and are subject to prepayment penalties and various non-financial covenants. We believe we were in compliance with all such covenants under the agreement as of December 31, 2013.

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, 2013 and 2012, and the related statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2013. Our audits also included the financial statement schedule listed in the Index at Item 15(a)2. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 also 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, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

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, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) and our report dated February 28, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2014

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

	December 31,	
	2013	2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 55,075	\$ 58,327
Investments in marketable securities	2,326	3,745
Restricted cash	548	640
Accounts receivable, net	9,300	6,152
Inventory	8,646	6,498
Prepaid expenses	1,902	1,064
Other current assets	91	90
Total current assets	<u>77,888</u>	<u>76,516</u>
Property and equipment, net	2,060	1,967
Intangible assets, net	10,747	12,090
Restricted cash	92	—
Other assets	16	7,106
Total assets	<u>\$ 90,803</u>	<u>\$ 97,679</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 7,724	\$ 5,796
Accrued liabilities	18,042	12,969
Deferred revenue	—	2,234
Current portion of long-term debt, less discount of \$252 and \$—, respectively	10,777	—
Total current liabilities	<u>36,543</u>	<u>20,999</u>
Long-term debt, less discount of \$433 and \$1,182, respectively	18,538	28,818
Other long-term liabilities	844	51
Total liabilities	<u>55,925</u>	<u>49,868</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, 2013 and 2012, respectively	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized, 86,719,716 shares and 85,668,668 shares issued and outstanding at December 31, 2013 and 2012, respectively	9	9
Additional paid-in capital	506,819	495,458
Accumulated other comprehensive income	—	—
Accumulated deficit	<u>(471,950)</u>	<u>(447,656)</u>
Total stockholders' equity	<u>34,878</u>	<u>47,811</u>
Total liabilities and stockholders' equity	<u>\$ 90,803</u>	<u>\$ 97,679</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,		
	2013	2012	2011
Revenues:			
Product revenue, net	\$ 110,529	\$ 50,066	\$ 11,486
License revenue	2,027	118	5,210
Total net revenues	<u>112,556</u>	<u>50,184</u>	<u>16,696</u>
Costs and expenses:			
Cost of product sales	37,973	23,256	12,406
Amortization of patent license	1,343	1,343	1,567
Research and development	6,743	6,519	8,885
Selling, general and administrative	94,482	86,843	81,504
Impairment of long-lived assets	—	7,723	—
Other	(441)	1,174	1,076
Total costs and expenses	<u>140,100</u>	<u>126,858</u>	<u>105,438</u>
Loss from operations	(27,544)	(76,674)	(88,742)
Other (expense) income:			
Interest income	69	123	136
Interest expense	(4,467)	(4,449)	(4,424)
Other income	7,648	27	9
Total other income (expense), net	<u>3,250</u>	<u>(4,299)</u>	<u>(4,279)</u>
Loss before income tax	<u>(24,294)</u>	<u>(80,973)</u>	<u>(93,021)</u>
Net loss	<u>\$ (24,294)</u>	<u>\$ (80,973)</u>	<u>\$ (93,021)</u>
Basic and diluted net loss per share ⁽¹⁾	<u>\$ (0.28)</u>	<u>\$ (0.95)</u>	<u>\$ (1.41)</u>
Shares used to compute basic and diluted net loss per share ⁽¹⁾	<u>85,969</u>	<u>85,556</u>	<u>66,075</u>

⁽¹⁾ As a result of the issuance of common stock pursuant to public offerings in the fourth quarter of 2011, 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 COMPREHENSIVE LOSS
(in thousands)

	<u>Year Ended December 31,</u>		
	<u>2013</u>	<u>2012</u>	<u>2011</u>
Net loss	\$(24,294)	\$(80,973)	\$(93,021)
Other comprehensive income (loss) gain:			
Net unrealized (loss) gain on securities available for sale	—	(2)	2
Other comprehensive income (loss) gain	—	(2)	2
Comprehensive loss	<u>\$(24,294)</u>	<u>\$(80,975)</u>	<u>\$(93,019)</u>

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
	Shares	Amount				
Balance at December 31, 2010	63,107	\$ 6	\$397,616	\$ —	\$ (273,662)	\$ 123,960
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
Net Loss	—	—	—	—	(93,021)	(93,021)
Balance at December 31, 2011	85,512	9	485,982	2	(366,683)	119,310
Issuance of warrants in December to purchase 155 shares of common stock at \$3.88 per share	—	—	416	—	—	416
Issuance of common stock from option exercises and lapse of restricted stock units under equity compensation plans	157	—	451	—	—	451
Stock-based compensation	—	—	8,609	—	—	8,609
Unrealized loss on marketable securities, net	—	—	—	(2)	—	(2)
Net Loss	—	—	—	—	(80,973)	(80,973)
Balance at December 31, 2012	85,669	9	495,458	—	(447,656)	47,811
Cashless warrant exercise in December at \$7.84 per share	128	—	—	—	—	—
Issuance of common stock from option exercises and lapse of restricted stock units under equity compensation plans	923	—	4,292	—	—	4,292
Stock-based compensation	—	—	7,069	—	—	7,069
Net Loss	—	—	—	—	(24,294)	(24,294)
Balance at December 31, 2013	86,720	\$ 9	\$506,819	\$ —	\$ (471,950)	\$ 34,878

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

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

	Year Ended December 31,		
	2013	2012	2011
Operating activities			
Net loss	\$(24,294)	\$(80,973)	\$(93,021)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	213	1,560	1,670
Loss (gain) on disposal of assets	—	873	(66)
Gain on sale of investment	(7,654)	—	—
Impairment of long-lived assets	—	7,723	—
Inventory write-down	—	163	5,574
Stock-based compensation	7,069	8,609	9,233
Non-cash interest expense	17	27	49
Amortization of intangible assets	1,343	1,343	1,567
Amortization of discount on note payable	497	122	409
Accretion of discounts on available-for-sale securities, net of accretion of premiums	(1)	(16)	5
Changes in operating assets and liabilities:			
Accounts receivable	(3,148)	(3,944)	(2,208)
Prepaid expenses and other assets	(830)	(78)	104
Inventory	(2,148)	(5,273)	(6,477)
Accounts payable	1,928	2,140	360
Deferred revenue	(2,234)	943	1,291
Accrued liabilities and other liabilities	6,049	2,482	3,358
Net cash used in operating activities	<u>(23,193)</u>	<u>(64,299)</u>	<u>(78,152)</u>
Investing activities			
Purchases of marketable securities	—	(1,397)	(82,681)
Maturities and sales of marketable securities	1,420	42,275	60,006
Payment for option purchase right	—	—	(3,500)
Proceeds from the sale of Incline options and preferred shares	14,654	—	—
Restricted cash	—	—	(300)
Purchases of property and equipment	(505)	(1,705)	(2,733)
Proceeds from the sale of property and equipment	80	393	66
Net cash provided by (used in) investing activities	<u>15,649</u>	<u>39,566</u>	<u>(29,142)</u>
Financing activities			
Proceeds from issuance of common stock	4,292	451	78,746
Borrowings under debt agreements, net of fees	—	—	3,434
Principal payments under debt agreements	—	—	(4,452)
Net cash provided by financing activities	<u>4,292</u>	<u>451</u>	<u>77,728</u>
Net decrease in cash and cash equivalents	(3,252)	(24,282)	(29,566)
Cash and cash equivalents at beginning of period	58,327	82,609	112,175
Cash and cash equivalents at end of period	<u>\$ 55,075</u>	<u>\$ 58,327</u>	<u>\$ 82,609</u>
Supplemental disclosures			
Issuance of warrants in connection with loan and security agreement	\$ —	\$ 416	\$ 390
Property and equipment purchases in accounts payable and accrued expenses	\$ 232	\$ 338	\$ 891
Cash paid for interest and fees	\$ 3,250	\$ 3,865	\$ 4,311

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 products principally for use in the hospital setting. In March 2006, the Company in-licensed the exclusive U.S. and Canadian rights to OFIRMEV® (acetaminophen) injection, an intravenous (“IV”) 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, 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. In January 2011, the Company commenced commercial sales of the product in the U.S.

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, the fair value of property and equipment, inventory obsolescence and valuation, restructuring liabilities, stock-based compensation, reserve for sales returns, 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.

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 discounts to certain group purchasing organizations, end-user hospitals, and government 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.

OFIRMEV, which was launched in January 2011, is the Company’s first and only commercially available product. Because the Company initially had limited product return data, it deferred the recognition of revenue on sales to wholesalers and, instead, recognized revenue at the time that product was sold by a wholesaler to an end-user customer. Shipments of product that were not recognized as revenue were treated as deferred revenue. However, as of January 1, 2013, the Company determined that it had obtained sufficient product return history to reasonably estimate future wholesaler returns. Since that time, the Company has recognized revenue at the time product is sold to a wholesaler. As a result of this change, the Company recorded a one-time adjustment to recognize revenue that had previously been deferred, resulting in additional net revenue of \$2,616,000 and cost of sales of \$919,000 for the year ended December 31, 2013. The corresponding impact of this one-time adjustment was a reduction of \$1,697,000 in both the Company’s loss from continuing operations and net loss for the year ended December 31, 2013, and the per share net impact of the adjustment was a reduction in net loss of

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

\$0.02 per share for the year. There was no similar impact on the reported revenue, cost of sales or loss per share for the years ended December 31, 2012 and 2011.

The Company records certain sales reserves and allowances as a reduction to gross revenue. These reserves and allowances include distribution service fees, a prompt payment discount, a group purchasing discount and administrative service fee, discounts to certain end-user customers and governmental programs and a reserve for estimated product returns based on historical return rates, 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 Company offers a prompt payment discount to 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 from 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. Administrative service fees for these transactions are also recorded at the time of sale. The Company also provides predetermined discounts under certain government programs, which are recorded at the time of sale.

Revenue from the Company's data license agreement with Terumo Corporation ("Terumo") is recognized separately for each element of the arrangement. Revenue from the data and services element that was provided to Terumo by the Company in 2011 and 2012 has been recognized upon delivery of the goods and services provided, based upon the consideration allocated to each deliverable, or the termination of the service period. The Company allocated the consideration from the data and services element to each deliverable based upon its review of the agreement pursuant to multiple-element arrangement guidance. Revenue from the first commercial sales milestone payment was recognized in November 2013 as the Company was able to confirm that the initial sale of Terumo's IV acetaminophen product had occurred in Japan. Royalties on subsequent sales will be recorded at the time the royalties can be reliably measured and collectability is reasonably assured. 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, wholesaler fees, chargebacks and doubtful accounts. 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. At December 31, 2013 and 2012, the Company's allowance for uncollectible receivables was \$19,000 and \$56,000, respectively. During the years ended December 31, 2013, 2012 and 2011 charges of \$3,000, \$56,000 and \$0, respectively, were taken to reserve for past due accounts. During the year ended December 31, 2013, past due accounts totaling \$40,000 that were previously reserved were written off. No past due accounts were written off during the years ended December 31, 2012 and 2011.

Fair Value Reporting

The Company's financial instruments consist of cash and cash equivalents, marketable securities, restricted cash, trade receivables and payables, 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

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

determined with precision. The carrying amount of cash and cash equivalents, restricted cash, trade receivables and payables and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. Further, based upon the borrowing rates currently available to the Company for loans with similar terms, the Company believes the fair value of long-term debt approximates its carrying value. The fair value of marketable securities is based upon market prices quoted on the last day of the fiscal period.

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, 2013 and 2012. The tables do not include assets and liabilities that are measured at historical cost or on any basis other than fair value (in thousands):

Description	Balance at December 31, 2013	Fair Value Measurements as of December 31, 2013		
		Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	\$ 48,975	\$48,975	\$ —	\$ —
Investments in marketable securities—short-term:				
Debt instruments—Municipal debt obligations	1,326	—	1,326	—
Certificates of deposit	1,000	—	1,000	—
Assets at fair value	<u>\$ 51,301</u>	<u>\$48,975</u>	<u>\$2,326</u>	<u>\$ —</u>

Description	Balance at December 31, 2012	Fair Value Measurements as of December 31, 2012		
		Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	\$ 55,736	\$55,736	\$ —	\$ —
Investments in marketable securities—short-term:				
Debt instruments—Corporate debt obligations	1,398	—	1,398	—
Debt instruments—Municipal debt obligations	1,347	—	1,347	—
Certificates of deposit	1,000	—	1,000	—
Assets at fair value	<u>\$ 59,481</u>	<u>\$55,736</u>	<u>\$3,745</u>	<u>\$ —</u>

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

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.

Cash Equivalents

The Company considers all highly liquid investments purchased with maturities of three months or less from the date of purchase 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, 2013 and 2012, the Company's cash equivalents were \$48,975,000 and \$55,736,000, 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 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. 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 (loss) 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. During the years ended December 31, 2013, 2012 and 2011, no realized gains or losses were recorded on the sale or maturity of the Company's marketable securities. Further, no impairments to reduce the value of an available-for-sale equity security were taken during the years ended December 31, 2013, 2012 and 2011. 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, marketable securities and accounts receivable. 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. Further, the Company specifies credit quality standards for its customers that are designed to limit the Company's credit exposure to any single party.

Manufacturing. The Company depends on an outsourced manufacturing strategy for its products. It has contracts in place with one third-party manufacturer that is approved for the production of OFIRMEV and one third-party manufacturer which is pending FDA approval.

Customers. The Company has entered into distribution agreements with 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. The Company's three primary wholesaler customers represented approximately 94% of the Company's product revenue for the year ended December 31, 2013, and 95% of the Company's accounts receivable balance at December 31, 2013. See Note 12 for further detail of the Company's 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. During the years ended December 31, 2012 and 2011, the Company recorded charges for inventory losses of \$163,000 and \$5,574,000, respectively, in cost of sales to write-down certain inventory manufactured to its estimated net realizable value. No charges for inventory losses were incurred for the year ended December 31, 2013. See “Supply Agreements” in Note 8 below for further information.

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, that range from the mid-teens to the mid-twenties, depending on the aggregate amount of net sales. The Company accrues 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 on the achievement of certain levels of annual 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, 2013, the Company had amortized an aggregate \$4,253,000 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. With respect to future milestone payments, at December 31, 2013, the Company had not yet achieved the levels of annual net sales necessary to require it to make payments under these milestone obligations, and therefore had not accrued for such potential payments in its financial statements. The Company will accrue for future milestone payments as they are anticipated and recognize the related expense in the period in which the milestone is achieved. See Note 9 for further discussion.

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 \$1,290,000, \$1,594,000 and \$2,181,000, respectively, for the years ended December 31, 2013, 2012 and 2011.

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 or, if the assets are impaired, at fair value. 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 fixtures; 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, 2013, 2012 and 2011, the Company recorded depreciation expense of \$213,000, \$1,560,000 and \$1,670,000, 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 the year ended December 31, 2012, the Company recorded a charge of \$6,973,000 to impair the value of its manufacturing assets and certain construction-in-process to their estimated fair value. The charge was due to the termination of a supply agreement with one of its third-party manufacturers. Additionally, the Company fully impaired its estimated asset retirement obligation related to the removal of the equipment located at that manufacturer's facility, resulting in an additional charge of \$750,000. During 2013, the Company removed its assets from the facility and fulfilled its asset retirement obligation for less than the estimated cost. As a result, the Company recorded a credit of \$136,000 during the year ended December 31, 2013, to relieve the accrued balance. No similar charges or credits were recorded during the year ended December 31, 2011. See Note 6 and Note 8 for further discussion.

Research and Development

The Company's research and development expenses consist primarily of 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, or all, 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.

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, 2013, the Company had issued both stock option awards and restricted stock units under its stock-based compensation plans. As of December 31, 2013 and 2012, all stock-based compensation awards were classified as equity awards.

Stock option awards. Stock options are valued using the Black-Scholes option pricing model. The Company values option awards on the date of grant or, if the awards are classified as liability awards, it revalues the awards each reporting period using this model until the awards are subsequently classified as equity awards, or otherwise vest. The Black-Scholes 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, 2013, 2012 and 2011, to determine the fair value of stock options granted during each period:

	Year Ended December 31,		
	2013	2012	2011
Risk free interest rates	1.2%	0.9%	2.2%
Expected life in years	6.0 years	5.7 years	6.2 years
Expected dividend yield	0.0%	0.0%	0.0%
Expected volatility	65.4%	72.0%	73.9%

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. The expected volatility is determined by incorporating the Company's historical stock price volatility and the implied volatility of its exchanged traded options. The assumed dividend yield is 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, 2013, 2012 and 2011 at \$3.45, \$1.86 and \$5.67, 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. The weighted-average grant date fair value of the RSUs granted in 2013 was \$8.31. There were no RSUs granted in 2012 or 2011.

Compensation expense for its service-based equity awards is recognized using the straight-line method. Stock-based compensation expense recognized during the period is based on the value of the portion of awards that is ultimately expected to vest. Hence, the gross expense is reduced for estimated forfeitures and adjusted for

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

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,		
	2013	2012	2011
Cost of product sales	\$ 277	\$ 343	\$ 297
Research and development	742	1,651	2,308
Selling, general and administrative	6,050	6,615	6,628
Total stock-based compensation expense included in loss from operations	<u>\$7,069</u>	<u>\$8,609</u>	<u>\$9,233</u>

The compensation expense related to unvested stock options and RSUs not yet recognized was approximately \$11,308,000 at December 31, 2013. This expense is expected to be recognized over a weighted-average period of approximately 32 months. The total fair value of shares vested during the years ended December 31, 2013, 2012 and 2011 was \$6,647,000, \$9,212,000 and \$9,852,000, 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) includes, among other items, 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, 2013 and 2012. 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 2013, 2012 and 2011 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, 2013, 2012 and 2011 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 21,800,000 common shares issued pursuant to a public offering in the fourth quarter of 2011. 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.

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NOTES TO FINANCIAL STATEMENTS—Continued

The Company incurred net losses for all periods presented and there were no reconciling items for potentially dilutive securities. More specifically, at December 31, 2013, 2012 and 2011, options, restricted stock units and warrants totaling approximately 16,734,000 shares, 16,677,000 shares and 14,457,000 shares, respectively, were excluded from the calculation as their effect would have been anti-dilutive.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*. ASU 2013-11 provides explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. The Company’s adoption of this guidance during the fourth quarter of 2013 did not have an impact on the Company’s financial statements for the period ended December 31, 2013.

3. Investments in Marketable Securities

In accordance with the Company’s investment policy, it has invested funds in marketable securities. The cost, gross unrealized holding gains, gross unrealized holding losses and fair value of these investments by types and classes of security at December 31, 2013 and December 31, 2012 consisted of the following (in thousands):

<u>At December 31, 2013</u>	<u>Amortized Cost Basis</u>	<u>Other-than- temporary Impairments</u>	<u>Gross Unrealized Holding Gains</u>	<u>Gross Unrealized Holding Losses</u>	<u>Fair Value</u>
<u>Available-for-sale:</u>					
Debt instruments—Municipal debt obligations	1,326	—	—	—	1,326
Certificates of deposit	1,000	—	—	—	1,000
	<u>\$ 2,326</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,326</u>
<u>At December 31, 2012</u>	<u>Amortized Cost Basis</u>	<u>Other-than- temporary Impairments</u>	<u>Gross Unrealized Holding Gains</u>	<u>Gross Unrealized Holding Losses</u>	<u>Fair Value</u>
<u>Available-for-sale:</u>					
Debt instruments—Corporate debt obligations	\$ 1,398	\$ —	\$ —	\$ —	\$ 1,398
Debt instruments—Municipal debt obligations	1,347	—	—	—	1,347
Certificates of deposit	1,000	—	—	—	1,000
	<u>\$ 3,745</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,745</u>

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

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

	December 31, 2013		December 31, 2012	
	Cost	Fair Value	Cost	Fair Value
Due or callable in one year or less	\$2,326	\$ 2,326	\$3,745	\$ 3,745
Due after one year	\$ —	\$ —	\$ —	\$ —

As of December 31, 2013 and 2012, there were no investments in unrealized loss positions.

4. Selected Financial Statement Data

	As of December 31,	
	2013	2012
Accounts receivable (in thousands):		
Trade accounts receivable	\$ 9,319	\$ 6,208
Allowance for doubtful accounts	(19)	(56)
	<u>\$ 9,300</u>	<u>\$ 6,152</u>
Inventory (in thousands):		
Raw materials	\$ 83	\$ 83
Finished goods	8,563	6,415
	<u>\$ 8,646</u>	<u>\$ 6,498</u>
Property and equipment (in thousands):		
Manufacturing equipment	\$ 2,801	\$ 2,999
Leasehold improvements	1,639	1,639
Computer equipment and software	1,613	1,489
Furniture and fixtures	478	478
Construction-in-process	961	724
	7,492	7,329
Less accumulated depreciation	(5,432)	(5,362)
Total	<u>\$ 2,060</u>	<u>\$ 1,967</u>
Accrued liabilities (in thousands):		
Accrued personnel costs	\$ 9,510	\$ 6,560
Accrued royalties payable	4,992	2,652
Accrued clinical trial costs	703	20
Accrued sales returns	369	—
Accrued asset retirement obligation	—	750
Other accrued liabilities	2,468	2,987
Total	<u>\$18,042</u>	<u>\$12,969</u>

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 (the "Option") to acquire Incline, which was developing IONSYS™ (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

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. Additionally, in consideration of the Company's expenditure of funds in connection with conducting its initial 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.

In December 2012, the Company and Incline entered into a Waiver, Consent and Option Termination Agreement (the "Waiver Agreement") pursuant to which the Company agreed to the buy-out and termination of its Option, contingent upon the closing of a separate agreement and plan of merger between Incline and The Medicines Company whereby The Medicines Company agreed to acquire Incline (the "Incline Acquisition"). In January 2013, The Medicines Company completed its acquisition of Incline. As consideration for entering into the Waiver Agreement and relinquishing its Option, the Company received a payment of \$13,125,000 upon the closing of the Incline Acquisition. The Company also received an additional payment of \$1,529,000 as consideration for the 500,000 shares of Incline Series A preferred stock held by the Company. The Company could also receive future milestone payments related to potential future licensing, regulatory approval and sales of the product candidate. Such milestones, if any, will be recorded as they are earned.

At the time the Option Agreement was entered, the Company determined that Incline was a variable interest entity ("VIE"). However, because it would not absorb a disproportionate amount of Incline's expected losses or receive a disproportionate amount of Incline's expected residual returns, the Company was not the primary beneficiary of this entity. Further, the Company did not have oversight of the day-to-day operations of Incline, nor did it have sufficient rights or voting representation to influence the operating or financial decisions of Incline, and the Company was not a founder of Incline and had no additional equity or funding requirements in future financings or otherwise. As such, the Company did not consolidate Incline into its financial statements. Alternatively, it valued its 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 with a carrying value of \$7,000,000. No adjustments were made to the carrying value of these assets prior to the closing of the Incline Acquisition in January 2013, and, as a result, the Company recorded a gain of \$7,654,000 in other income during the year ended December 31, 2013. No similar gains were recorded during the years ended December 31, 2012 and 2011.

The \$7,000,000 carrying value of the Company's Incline investment was recorded as other long-term assets on the Company's balance sheet at December 31, 2012.

6. Restructuring and Impairment Charges

In February 2012, the Company observed particulate matter during routine product stability testing of OFIRMEV that was manufactured at one of its third-party manufacturers, Baxter. As a result, the Company decided to suspend further production by Baxter. In March 2013, the Company and Baxter mutually agreed to terminate the supply agreement for OFIRMEV. As a result, the Company reduced the carrying value of its manufacturing assets and its manufacturing equipment and facility construction assets in process to their current estimated fair value as of December 31, 2012, resulting in an impairment charge of \$6,973,000 during the year. The fair value of these assets was determined through a third-party valuation assessment based upon research of market prices for similar equipment and the Company's prior experience with asset disposals. The determination of the fair value of the manufacturing assets was considered a Level 3 measurement. The Company also fully impaired the retirement obligation asset related to the removal of the equipment as of December 31, 2012, resulting in a charge of \$750,000 during the year. No such obligation had been recorded as of December 31, 2011. See further discussion of the Baxter agreement in Note 8.

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

In November 2011, the Company restructured its workforce to focus its resources on the commercialization of OFIRMEV and reduce program costs not directly associated with such efforts. 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. During 2012, the Company disbursed the remaining severance benefits and as of December 31, 2012, no restructuring liability remained on the balance sheet.

7. Loan and Security Agreement

In December 2012, the Company entered into a First Amendment to Second Amended and Restated Loan and Security Agreement (the “2012 Amendment”) with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation (collectively, the “Lenders”), which amended and restated the Company’s previous Second Amended and Restated Loan and Security Agreement entered into in December 2011 (the “2011 Amendment”). Pursuant to the terms of the 2012 Amendment, the Company made interest-only payments through December 2013, and in January 2014, began to make equal monthly principal and interest payments to fully amortize the balance over the remaining 30-month term. The stated interest rate under the 2012 Amendment is 10.9545% and the Company will be required to make a final payment of 6% of the total advance at the termination of the loan.

At the time of closing the 2012 Amendment, the Company made a term loan final payment of \$752,000 in accordance with the terms of the 2011 Amendment, which had been amortized over the term of the 2011 Amendment, and paid customary closing fees and expenses of \$18,000 in connection with the closing of the 2012 Amendment. Additionally, the Company issued warrants to purchase 154,638 shares of the Company’s common stock, as detailed below, to the Lenders in connection with the 2012 Amendment at an exercise price \$3.88 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. Further, 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 2012 Amendment, 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 prepayment penalties and certain financial and non-financial covenants, including the maintenance of minimum quarterly product revenue of at least \$12,500,000. Upon the occurrence of an event of default, including a Material Adverse Change (as defined in the 2011 Amendment), the lenders may declare all outstanding amounts due and payable under the 2012 Amendment. As of December 31, 2013, the Company was in compliance with all covenants under the 2012 Amendment.

The Company determined that the terms of the 2012 Amendment were not substantially different than the 2011 Amendment and accounted for the transaction as a loan modification. As such, the fair value of the warrants issued in connection with the 2012 Amendment and the carrying value of the issuance costs and discount related to the 2011 Amendment were aggregated and are being amortized to interest expense throughout the life of the 2012 Amendment using an effective interest rate of 15.30%. Similarly, in connection with the 2011 Amendment, the Company determined that the terms were not substantially different than the 2010 Amendment and therefore accounted for the transaction as a loan modification of the 2010 Amendment. The 2011 Amendment provided the Company with \$3,434,000 of additional net capital after deducting a \$954,000 term loan final payment paid under the 2010 Amendment and customary closing fees and expenses of \$63,000 paid in connection with the closing of the 2011 Amendment. As part of the 2011 Amendment, the Company issued

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

warrants to purchase an aggregate of 158,311 shares of the Company's common stock to the Lenders, as detailed below, and classified the warrants as equity, recognizing the fair value as a discount on the loan issuance. The fair value of the warrants was aggregated with the carrying value of the issuance costs and discount related to the 2010 Amendment, and was being amortized over the term of the 2011 Amendment using an effective interest rate of 15.31% prior to the 2012 Amendment.

As of December 31, 2013 and 2012, 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 2012 Amendment as of December 31, 2013 were as follows (in thousands):

2014	\$ 13,772
2015	13,772
2016	8,686
Total future payments	36,230
Less amount representing interest and fees	(6,230)
Gross balance of long-term debt	30,000
Less unamortized discount	(685)
Total carrying value of long-term debt	29,315
Less current portion	(10,777)
Long-term portion	<u>\$ 18,538</u>

Warrants

In connection with the establishment of the Company's credit facilities and related amendments, including the 2012 Amendment, the Company has issued warrants to the Lenders to purchase shares of the Company's common stock. The table below summarizes the issuances of such warrants currently outstanding, including the Black-Scholes valuation model assumptions used to determine the fair value of the warrants:

	Date of Issuance			
	December 2012	December 2011	June 2010	November 2007
Aggregate shares pursuant to warrants issued	154,638	158,311	254,793	50,331
Per share exercise price of warrants issued	\$ 3.88	\$ 3.79	\$ 7.0645	\$ 12.67
Fair value of warrants issued	\$ 416,000	\$ 390,000	\$ 1,237,000	\$ 474,000
Expiration date of warrants	December 9, 2019	December 22, 2018	June 18, 2017	November 30, 2014
Black-Scholes valuation inputs:				
Expected volatility	70.17%	72.40%	76.50%	70.00%
Risk-free interest rate	1.02%	1.40%	2.70%	3.64%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Expected term	7 years	7 years	7 years	7 years

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

As of December 31, 2013, the aforementioned warrants to purchase 618,073 shares of the Company's common stock were outstanding.

8. Commitments and Contingencies

Leases

In May 2006, the Company entered into an operating lease for corporate 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 was reduced commencing in April 2012 and the Company returned a portion of the leased space in September 2012. In September 2013, the Company entered into a third amendment to the lease agreement (the "Third Amendment"), pursuant to which the Company expanded its rented space for a term from January 1, 2014, through May 31, 2019. The Company also has the right to renew the lease for one additional five-year term. The terms of the lease include a one-time tenant improvement allowance of up to \$475,000, which the Company will record as the improvements are completed, and which will be amortized ratably over the shorter of the useful life or the remaining life of the lease. As of December 31, 2013, no such improvements had been completed.

As security for the initial lease, the landlord required a letter of credit, which is collateralized by a certificate of deposit in the same amount, and which the Company has classified as restricted cash on its balance sheet. As of December 31, 2013 and 2012, the amount of each of the letter of credit and the corresponding certificate of deposit was \$190,000. The security deposit required by the landlord will be reduced pursuant to the Third Amendment to \$92,000, effective January 1, 2014.

The Company also leases certain office equipment under capital and operating leases. Its current capital lease has a term of four years and expires in 2016. As of December 31, 2013 and 2012, the assets under its current capital lease had a gross value of \$56,000. During the years ended December 31, 2013 and 2012, the Company recorded amortization expense of \$14,000 and \$1,000, respectively, related to these assets. The remaining obligation under its capital lease at December 31, 2013 is recorded on the Company's balance sheet in accrued expenses and other long-term liabilities at \$12,000 and \$29,000, respectively. No assets were recorded under capital leases as of December 31, 2011.

As of December 31, 2013, the total future minimum payments under its operating and capital leases, including rent and office equipment, were as follows (in thousands):

2014	\$ 600
2015	1,006
2016	1,030
2017	1,043
2018	1,074
Thereafter	461
Total	<u>\$5,214</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 under the Company's facility and equipment leases for the years ended December 31, 2013, 2012 and 2011 was \$709,000, \$927,000 and \$928,000, respectively.

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

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. At December 31, 2013, the Company maintained the pledge agreement and the funds under the agreement are classified as restricted cash on the Company's balance sheet at December 31, 2013 and 2012, respectively.

Supply Agreements

Lawrence Laboratories

In February 2013, the Company entered into an Amended and Restated Supply Agreement (the "Supply Agreement") with Lawrence Laboratories, an operating division of Swords Laboratories, and a member of the BMS group of companies, which amended and restated the original agreement entered into between the parties in December 2010, for the manufacture of commercial supplies of the finished drug product for OFIRMEV packaged in vials (the "Product"), for sale and distribution by the Company in the United States and Canada. Bristol-Myers Squibb Srl ("BMS Anagni"), an indirect subsidiary of BMS located in Anagni, Italy, manufactures the Product on behalf of Lawrence Laboratories. BMS Anagni is currently the Company's sole supplier of OFIRMEV.

Pursuant to the terms of the Supply Agreement, the Company pays Lawrence Laboratories a set price for each unit of Product purchased, based upon the aggregate quantity of Product the Company has specified that it intends to order during a calendar year, and whether Lawrence Laboratories has implemented certain agreed-upon manufacturing capacity increase improvements. The Company is obligated to purchase a minimum number of units each year, or pay Lawrence Laboratories an amount equal to the shortfall between the minimum purchase requirement and the number of units of Product actually ordered during such year, multiplied by a pre-set amount that also varies depending upon whether Lawrence Laboratories has implemented certain agreed-upon manufacturing capacity increase improvements. The Company is obligated to purchase at least 75% of its annual Product requirements from Lawrence Laboratories each contract year. The Supply Agreement also requires the Company to pay Lawrence Laboratories for additional services requested by the Company at a specified hourly rate and for any validation batches that may be required by the Company, not to exceed a specified rate. All amounts payable under the Supply Agreement are paid in U.S. dollars.

The term of the Supply Agreement extends through December 31, 2018, unless extended by mutual agreement of the Company and Lawrence Laboratories, or unless the Supply Agreement is terminated sooner: (1) by the mutual agreement of the parties, (2) by either party for convenience following 24 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 Supply Agreement. In addition, either party may terminate the Supply Agreement: (a) within 60 days, after written notice in the event of a material uncured breach of the Supply 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 Supply Agreement is terminated by the Company for its convenience or by Lawrence Laboratories due to the Company's material breach of the Supply Agreement, the Company will reimburse Lawrence Laboratories for: (1) any Product ordered under a firm order and received by the Company, and (2) any inventory of materials used to manufacture the Product that are specific to the Product and that Lawrence Laboratories is unable to reasonably utilize. Additionally, the Company's minimum purchase requirement for the year in which

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

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 Supply Agreement is terminated for any reason other than by the Company for its convenience or by Lawrence Laboratories due to the Company's material breach of the Supply Agreement, the Company will not be required to reimburse Lawrence Laboratories for any inventory of materials used to manufacture the Product, 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.

Purchases under the current agreement were \$17,600,000 during the year ended December 31, 2013, which was sufficient to meet the minimum purchase commitment. Future minimum purchase requirements under this agreement at December 31, 2013 are as follows (in thousands):

2014	\$16,050
2015	15,750
2016	15,750
2017	15,750
2018	15,750
Thereafter	—
Total	<u>\$79,050</u>

Grifols

In March 2013, the Company entered into an agreement with Laboratorios Grifols, S.A. ("Grifols"), a division of Grifols, S.A., a global healthcare company headquartered in Barcelona, Spain, for the development, manufacture and supply of commercial quantities of OFIRMEV in flexible IV bags. Grifols has supplied IV acetaminophen in flexible plastic bags to BMS for distribution in certain markets outside of the U.S. and Canada since 2010. The Company submitted a supplemental NDA to the FDA in the fourth quarter of 2013 seeking approval of the product to be manufactured by Grifols.

Pursuant to the terms of the agreement, the Company will pay Grifols a set price for the OFIRMEV it purchases, which may be adjusted annually by Grifols, subject to specified limitations. In addition, the Company will be obligated to pay Grifols a reservation fee, in lieu of any minimum purchase commitment, calculated by multiplying the shortfall between the annual production capacity it has reserved with Grifols and the amount of product actually ordered during that year by a fixed amount. Pending review and subsequent approval of the submission by the FDA, the agreement will terminate on the sixth anniversary of the approval by the FDA of the product manufactured by Grifols, unless it is terminated sooner by the Company upon the termination of its license agreement for the product with BMS, or after 60 days' written notice following the discontinuation of the distribution of the product by the Company. In addition, either party may terminate the agreement after 60 days' written notice in the event of a material uncured breach of the agreement by the other party (or 30 days in the case of a payment default), or immediately upon an insolvency event.

Baxter Healthcare Corporation

In July 2007, the Company entered into a development and supply agreement (the "Baxter Supply Agreement") with 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. In January 2011, the Company amended and restated the Baxter Supply Agreement (the "Amended Supply Agreement") in connection with a plan to expand the manufacturing capacity for OFIRMEV at Baxter.

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

In February 2012, the Company announced a voluntary recall of a single lot of OFIRMEV that was manufactured at Baxter's facility due to the presence of an unidentified, visible particle in that lot during routine stability testing. The Company also placed certain finished product inventory of OFIRMEV manufactured by Baxter on indefinite hold and decided to suspend further production by Baxter. In July 2012, the Company announced a second voluntary recall of the remaining 41 unexpired lots of OFIRMEV manufactured at Baxter's facility due to the presence of unidentified, visible particles in a limited number of vials from one lot of the product, which were detected during routine stability testing. Although the Company received no adverse event reports associated with the particulate matter, and no product complaints involving similar particulate matter have been received, the Company decided to recall the remaining lots of OFIRMEV manufactured by Baxter as a precautionary measure. All of the 41 recalled lots, which were manufactured between January and March 2011, had expired by December 31, 2012. In March 2013, the Company and Baxter mutually agreed to terminate the Amended Supply Agreement for OFIRMEV. As part of the settlement and termination with Baxter, the Company agreed that it would be responsible for the removal of the equipment, which the Company estimated would cost approximately \$750,000. Accordingly, it recorded this retirement obligation on its balance sheet at December 31, 2012 as the conditions existed under the terms of the Amended Supply Agreement at that time. Further, as of December 31, 2012, the Company fully impaired this retirement obligation asset and recognized a charge of \$750,000 in its statement of operations for the year ended December 31, 2012. The Company subsequently completed the removal of the equipment and released the remaining balance of the accrued obligation, resulting in a gain of \$136,000 during the third quarter of 2013, which was recorded in other operating expenses. No similar gains were recorded during the years ended December 31, 2012 and 2011. Also pursuant to the settlement, a previously accrued liability of \$317,000 related to an outstanding product order was canceled, which was recorded in cost of sales during the first quarter of 2013.

As a result of the initial recall, the Company recorded charges of \$5,574,000 for the fourth quarter of 2011 and \$163,000 for the first quarter of 2012 to fully write-down the value of the inventory placed on hold. As a result of the second recall, the Company decided to destroy the product that was previously placed on hold and accrued for estimated destruction charges, recording \$290,000 and \$50,000 in other operating expenses for the years ended December 31, 2012 and 2013, respectively. In addition, the Company incurred costs associated with these recalls, including administration costs, of approximately \$300,000 through December 31, 2013. As of December 31, 2013, the recall had been substantially completed and further returns are expected to be minimal, if any. The costs related to the recalls are being recognized as selling, general and administrative expenses on the Company's statement of operations as they are incurred. The charge to reduce the value of the inventory was recorded as a cost of product sales on the Company's statement of operations during the period in which the impairment was taken. As of December 31, 2013, no accrued destruction charges remained on the Company's balance sheet.

Due to the termination of the Amended Supply Agreement with Baxter, the Company reduced the carrying value of its manufacturing assets and its manufacturing equipment and facility construction assets in process to their current estimated fair value, resulting in an impairment charge of \$6,973,000 for the year ended December 31, 2012. The fair value of these assets was determined through a third-party valuation assessment and market prices for similar assets. Further, in December 2012, the Company sold a construction-in-process asset resulting in a loss on the disposal of \$858,000. These assets were classified as held and used at December 31, 2012, as a formal plan to sell the assets, or otherwise dispose of them, had not been implemented at that time. The Company continues to assess the classification of these assets and has determined that, based upon relevant guidance, the assets continue to be considered held and used at December 31, 2013.

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

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 SCR Pharmatop S.A. (“Pharmatop”) and the Company has the right to grant sublicenses to third parties. As consideration for the license, the Company paid a \$25,000,000 up-front fee in March 2006 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 which range 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 June 2013, Health Canada issued a Notice of Compliance that granted marketing approval for OFIRMEV in Canada. The Company has not determined the commercial feasibility of launching the product in Canada, either independently or in collaboration with a company with an existing Canadian commercial presence, because it has not yet received a pricing review from the Canadian Patented Medicine Prices Review Board (“PMPRB”). The Company submitted a pricing review application for OFIRMEV to the PMPRB in October 2013.

In November 2010, the Company entered into a data license agreement among Terumo Corporation (“Terumo”), the Company and 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 commercialization of, the same IV formulation of acetaminophen in Japan. Further, the Company provided technical assistance and consulting services to Terumo at no charge regarding the licensed technical information, data and know-how, 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.

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 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 recognized the consideration allocated to the data license upon delivery and recognized the consideration allocated to the consulting services as such services were 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 and in April 2011, the Company recognized \$5,210,000 of license revenue pursuant to the agreement for the data transfer and consulting hours provided. During 2012, the Company recognized the remaining balance of \$118,000 as license revenue.

In June 2013, the Company was notified that Terumo received regulatory approval for its IV acetaminophen product from the Japanese Ministry of Health, Labour & Welfare. In November 2013, Terumo commenced commercial sales of its product and pursuant to the terms of the data license agreement, the Company received from Terumo a non-refundable payment of \$2,027,000 which was recorded as licensing revenue during the year ended December 31, 2013. In addition, the Company is entitled to royalty payments on the product’s commercial sales in

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

Japan, which will be recognized as royalty revenue in the quarter in which Terumo provides the necessary sales information. No royalty revenue was recognized for the years ended December 31, 2013, 2012 and 2011.

10. Legal Matters

'222 and '218 Patent Litigation; Exela Pharma Sciences, LLC and Paddock Laboratories, Inc. (Perrigo Company)

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 referred to herein as Perrigo, and against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc., collectively referred to herein as Exela. The lawsuit followed the notices that the Company received in July 2011 from each of Perrigo 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 alleged that Perrigo and Exela 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 Perrigo 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 Perrigo or Exela, or such shorter or longer period as the Court may order. Each of Perrigo and Exela filed an answer in the case asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims.

The Company settled with Perrigo and the case against Perrigo was dismissed on November 30, 2012. In connection with the settlement and license agreements entered into in November 2012, Perrigo was granted the exclusive right of first refusal to negotiate an agreement with the Company to market an authorized generic version of OFIRMEV in the U.S. in the event that the Company elects to launch an authorized generic version of the product. The license agreement also provides that, if the Company enters into an agreement for Perrigo to market an authorized generic version of OFIRMEV during the license period, Perrigo would purchase the product exclusively from the Company. The Company would receive product costs plus an administrative fee, as well as a royalty payment based on the net profits achieved by Perrigo from the sale of the authorized generic product. Additionally, the Company granted Perrigo the non-exclusive right to market a generic IV acetaminophen product in the U.S. under Perrigo's ANDA after December 6, 2020, or earlier under certain circumstances. The Federal Trade Commission, or FTC, or the Department of Justice, or DOJ, could seek to challenge the Company's settlement with Perrigo, or a competitor, customer or other third-party could initiate a private action under antitrust or other laws challenging the Company's settlement with Perrigo.

A bench trial for the lawsuit with Exela was held in May 2013, with one additional trial date held in early July 2013. In November 2013, the court ruled in favor of us and found that Exela's ANDA for a generic version of OFIRMEV infringed the '222 and '218 patents. An appeal of the decision in favor of us was filed by Exela on December 20, 2013. It is not possible to predict the outcome of this appeal, and an adverse outcome could result in the launch of one or more generic versions of OFIRMEV before the expiration of the last of the listed patents on June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted), which could adversely affect the Company's ability to successfully maximize the value of OFIRMEV, and would negatively impact the Company's financial condition and results of operations, including causing a significant decrease in the Company's revenues and cash flows.

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

'222 and '218 Patent Litigation: Fresenius Kabi USA, LLC, Sandoz, Inc. and Wockhardt USA LLC

In January 2013, the Company filed suit in the United States District Court for the Southern District of California against Fresenius Kabi USA, LLC, or Fresenius, following receipt of a December 2012 notice from Fresenius concerning its submission of an NDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In February 2013, the Company filed suit in the United States District Court for the Southern District of California against Sandoz, Inc., or Sandoz, following receipt of a December 2012 notice from Sandoz concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In October 2013, the Company filed a motion to amend the complaint against Sandoz to join Sandoz AG, Neogen International N.V., APC Pharmaceuticals, LLC, and DIACO, S.p.A. (together with Sandoz, the Sandoz Parties) to the lawsuit against Sandoz due to the involvement of each of these companies in the preparation of the Sandoz ANDA and related matters.

In the lawsuits against Fresenius and the Sandoz Parties, which were coordinated for purposes of discovery and other pretrial proceedings in the Southern District of California, the Company alleged that Fresenius and the Sandoz Parties each infringed the '222 patent and the '218 patent by filing an NDA, in the case of Fresenius, or an ANDA, in the case of the Sandoz Parties, seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Both Fresenius and the Sandoz Parties filed answers in the Southern District of California asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims. Both the Fresenius and Sandoz lawsuits were filed within 45 days of receipt of the respective notice letters, thereby triggering a stay of FDA approval of the Fresenius NDA and the Sandoz 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 Fresenius and/or the Sandoz Parties, or such shorter or longer period as the court may order.

In January 2014, the Company entered into a settlement agreement and a binding term sheet for a license agreement with the Sandoz Parties. The settlement agreement includes a stipulation by the parties requesting dismissal with prejudice of the lawsuit filed by the Company relating to the ANDA filed by Sandoz. Under the terms of the license, the Company granted to the holder of the Sandoz ANDA and its affiliates the non-exclusive right to market a generic intravenous acetaminophen product in the United States under the Sandoz ANDA beginning December 6, 2020, or earlier under certain circumstances. The Company also agreed that in the event that it determines to launch an authorized generic version of OFIRMEV (i.e., a generic version marketed under its NDA) in the U.S. and Perrigo elects not to exercise its right of first refusal to become the distributor of the authorized generic version of the product, the Company will grant a similar right of first refusal to the holder of the Sandoz ANDA on substantially the same terms as those previously granted to Perrigo. In addition, the license agreement will contain provisions regarding indemnification, confidentiality and other customary provisions for agreements of these kinds. The settlement documents are subject to submission to the Federal Trade Commission and the U.S. Department of Justice. Litigation remains ongoing against Fresenius, and the bench trial for such lawsuit is tentatively scheduled to commence on July 14, 2014.

In December 2013, the Company received a notice from Wockhardt USA LLC, or Wockhardt, stating that Wockhardt filed an ANDA containing a Paragraph IV patent certification with the FDA for a generic version OFIRMEV. This notice stated that the Paragraph IV patent certification was made with respect to both the '222 patent and the '218 patent. The Company filed suit against Wockhardt Limited, Wockhardt BIO AG and Wockhardt on January 22, 2014 in the U.S. District Court of Delaware, and on January 23, 2014, in the U.S. District Court of New Jersey.

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

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

August 5, 2017 (or February 5, 2018 if pediatric exclusivity is granted) and the '218 patent expires June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted). However, given the unpredictability inherent in litigation, the Company cannot predict the outcome of these matters or any other litigation.

'222 and '218 Patents: Ex Parte Reexamination

In September 2012, an unidentified third party (subsequently identified as Exela) filed with the United States Patent and Trademark Office, or USPTO, a Request for Ex Parte Reexamination of the '222 patent. In December 2012, the Company received notice that the USPTO had granted the Request for Reexamination. The reexamination process is provided for by law and requires the USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO. In February 2013, Cadence and Pharmatop filed with the USPTO a patent owner's statement commenting on the reexamination request, and in April 2013, Exela filed comments in response to the patent owner's statement. In a non-final, initial office action issued by the USPTO on August 13, 2013, the USPTO rejected certain claims of the '222 patent. A response to the first office action was filed in November 2013.

In addition, in January 2014, an unidentified third party filed with the USPTO a Request for Ex Parte Reexamination of the '218 patent. All of the claims of the '222 and '218 patents remain valid and in force during the reexamination proceedings. Because the Company and Pharmatop believe that the scope and validity of the patent claims in these patents are appropriate and that the USPTO's prior issuances of the patents were correct, the Company, in conjunction with Pharmatop, will vigorously defend these patents. The Company cannot predict whether it and Pharmatop ultimately will succeed in maintaining the scope and validity of the claims of these patents during reexamination. If any of the patent claims in these patents ultimately are narrowed during prosecution before the USPTO, the extent of the patent coverage afforded to OFIRMEV could be impaired, which could potentially harm the Company's business and operating results.

'218 Patent Litigation: Exela Pharma Sciences, LLC

In April 2012, Exela filed suit against David J. Kappos and the USPTO in the United States District Court for the Eastern District of Virginia for declaratory judgment seeking a reversal of the USPTO's decision not to act on a petition by Exela to vacate the USPTO's April 2003 order reviving the international application for the '218 patent. The lawsuit followed the USPTO's rejection of Exela's petition to the USPTO filed in November 2011, which sought to vacate the April 23, 2003 order granting Pharmatop's petition to revive the '218 patent. The USPTO determined that Exela lacked standing to seek such relief. Exela also seeks declaratory judgment that the USPTO's rules and regulations that allow for revival of abandoned, international patent applications under the "unintentional" standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. The Company's motion to intervene in this lawsuit was granted in October 2012. In December 2012, the district court dismissed the case with prejudice as barred by the applicable statute of limitations. In February 2013, Exela appealed the district court's decision to the Court of Appeals for the Federal Circuit. The Court of Appeals heard oral argument on the appeal in February 2014. A decision by the Court of Appeals in favor of Exela could result in the invalidation of the '218 patent.

Stockholder Class-Action Litigation Regarding the Company's Pending Acquisition by Mallinckrodt plc

Following the February 11, 2014, announcement that the Company had entered into an agreement and plan of merger with Mallinckrodt plc and a subsidiary of Mallinckrodt, six putative class-action lawsuits were filed in the Court of Chancery of the State of Delaware: *Wolfson v. Cadence Pharmaceuticals, Inc., et al.*, No. 9341-VCP (filed February 12, 2014); *Goode v. Garner, et al.*, No. 9361-VCP (filed February 18, 2014); *Bushansky v.*

CADENCE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS—Continued

Cadence Pharmaceuticals Inc., et al., No. 9365-VCP (filed February 19, 2014); *Bokol v. Cadence Pharmaceuticals Inc., et al.*, No. 9367 (filed February 19, 2014); *Elvir v. Cadence Pharmaceuticals Inc., et al.*, No. 9370-VCP (filed February 19, 2014); and *Nguyen v. Cadence Pharmaceuticals, Inc., et al.*, No. 9376-VCP (filed February 21, 2014). Two substantially identical putative class-action lawsuits were filed in the Superior Court of California, County of San Diego: *Denny v. Cadence Pharmaceuticals, Inc., et al.*, No. 37-2014-00002579-CU-BT-CTL (filed February 13, 2014) and *Militello v. Cadence Pharmaceuticals, Inc., et al.*, No. 37-00003634-CU-BT-CTL (filed February 20, 2014). The complaints allege that members of the Company's board of directors breached their fiduciary duties to the Company's stockholders in connection with the proposed transaction and that the merger agreement involves an unfair price, an inadequate sales process, and unreasonable deal protection devices that purportedly preclude competing offers. The complaints other than *Bushansky* further allege that the Company, Mallinckrodt, and/or its subsidiary aided and abetted the alleged breaches of fiduciary duties. The lawsuits seek an injunction against the consummation of the merger and rescission of the merger agreement to the extent the merger may already be consummated prior to the entry of the court's final judgment, and an award of costs and expenses, including attorneys' and experts' fees.

The Company intends to vigorously defend against these claims. The outcome of this litigation cannot be predicted at this time and any outcome in favor of the plaintiffs could have an adverse effect on the proposed transaction, the Company's financial condition, and the Company's results of operations.

At this time, the Company is unable to estimate possible losses or ranges of losses for any of its current litigation, and it has not accrued any amounts for current litigation other than ongoing attorney's fees.

11. Stockholders' Equity

Authorized Shares

In June 2012, following approval by the Company's stockholders, the Company filed a Certificate of Amendment of Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, which increased the number of authorized shares of common stock of the Company from 100,000,000 to 200,000,000.

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. The 2011 offering raised proceeds, net of offering costs and underwriting discounts and commissions, of \$77,302,000.

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. During December 2013, warrants to purchase an aggregate of 590,893 shares of the Company's common stock were exercised at a price of \$10.01, resulting in a total of 128,095 shares issued on a net exercise basis. As of December 31, 2013, warrants related to the private placement to purchase up to 5,429,004 additional shares of the Company's common stock remained outstanding.

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

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, 2013, options to purchase 75,816 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, 2013, the board of directors approved the amount of shares authorized for future issuance under the 2006 Plan to be increased by an aggregate 11,853,707 shares under this provision.

As of December 31, 2013, the Company had issued both stock options and restricted stock units (“RSUs”) 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, 2013:

	<u>Authorized</u>	<u>Available</u>	<u>Outstanding</u>
2004 Equity Incentive Plan	2,708,412	—	742,685
2006 Equity Incentive Plan	14,120,295	3,125,966	9,944,220
	<u>16,828,707</u>	<u>3,125,966</u>	<u>10,686,905</u>

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

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

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, however certain grants to the Company's executive officers have been made in lieu of their annual bonus awards and vest over a term of generally less than one-year. In addition, annual grants to the Company's board members vest over a period of one-year. The exercise price of the Company's stock options shall not be less than 100% of the fair value of the Company's common stock on the date of grant. Further, 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, 2013, and changes for the year then ended:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life - Years	Aggregate Intrinsic Value
Options outstanding at beginning of period	10,037,984	\$ 6.81		
Granted	2,208,750	\$ 5.84		
Exercised	(922,141)	\$ 4.65		
Cancelled	(640,688)	\$ 8.13		
Options outstanding at end of period	<u>10,683,905</u>	<u>\$ 6.72</u>	<u>6.83</u>	<u>\$28,675,000</u>
Options exercisable at end of period	<u>6,729,953</u>	<u>\$ 7.39</u>	<u>5.81</u>	<u>\$14,926,000</u>

The aggregate intrinsic value of options exercised during 2013, 2012 and 2011 was \$2,921,000, \$175,000 and \$2,774,000, respectively. During 2013, the Company received \$4,292,000 upon the exercise of stock options in satisfaction of the exercise price.

Restricted Stock Units

The Company has granted a limited number of RSUs with vesting schedules based upon performance criteria, service conditions or a combination of both performance criteria and service conditions. During 2013, the Company granted 3,000 RSUs, all of which remained outstanding as of December 31, 2013.

The following table summarizes the Company's RSU activity as of December 31, 2013, 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	938	\$ 10.38	
Granted	3,000	\$ 8.31	
Vested	(938)	\$ 10.38	
Cancelled	—	—	
Restricted stock units outstanding at end of period	<u>3,000</u>	<u>\$ 8.31</u>	<u>\$ 27,000</u>

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

The aggregate intrinsic value of RSUs vested during 2013, 2012 and 2011 was \$5,000, \$6,000 and \$716,000, respectively. During 2013, a total of 126 vested shares were withheld from distribution in satisfaction of statutory minimum tax obligations and the Company used less than \$1,000 to satisfy such tax obligations.

12. Segment Information

Operating segments are identified as components of an enterprise for 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. The Company operates and manages its business as 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.

The Company had three major customers, each representing 10% or more of total gross product revenue for the periods presented as follows:

	Year Ended December 31,		
	2013	2012	2011
AmerisourceBergen Corporation.	35%	33%	33%
Cardinal Health, Inc.	32%	33%	37%
McKesson Corporation	27%	27%	23%

Receivables from these customers at December 31, 2013 and 2012 amounted to the following percentages of total gross accounts receivable:

	As of December 31,	
	2013	2012
AmerisourceBergen Corporation	36%	32%
Cardinal Health, Inc.	32%	31%
McKesson Corporation	27%	31%

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, 2013 and 2012, and has recognized no interest and/or penalties in the Company's statement of operations for the years ended December 31, 2013, 2012 and 2011.

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. During the second quarter of 2013, the Company completed an analysis under IRC Sections 382 and 383 through December 31, 2012, and determined that it experienced an ownership change in March 2006. However, this ownership change did not result in the forfeiture of any net operating losses or research and development credits. Therefore, the Company has reinstated

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

the (1) deferred tax assets for net operating losses of approximately \$149,071,000 and (2) research and development credits of approximately \$6,809,000 generated through 2012 to its deferred tax asset schedule. Further, the Company has recorded a corresponding increase to its valuation allowance. The analysis did not have any impact on the Company's unrecognized tax benefits. There is risk that additional changes in ownership have occurred since the completion of the Company's analysis, which was through December 31, 2012. If a change in ownership were to have occurred, additional net operating loss and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

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 net deferred tax assets for federal and state income taxes at December 31, 2013 and 2012 are shown below (in thousands):

	As of December 31,	
	2013	2012
Deferred tax assets:		
Net operating loss carryforwards	\$ 157,484	\$ —
Tax credit carryforwards	5,781	—
Stock-based compensation	13,983	12,876
Capitalized research and development	4,535	5,348
Other, net	4,208	5,954
	<u>185,991</u>	<u>24,178</u>
Valuation allowance for deferred tax assets	<u>(185,987)</u>	<u>(23,272)</u>
Net deferred tax assets	<u>\$ 4</u>	<u>\$ 906</u>
Deferred tax liabilities:		
Deferred tax liabilities	<u>(4)</u>	<u>(906)</u>
Net deferred tax liabilities	<u>\$ (4)</u>	<u>\$ (906)</u>
Net deferred tax assets	<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,		
	2013	2012	2011
Federal income taxes	35.0%	35.0%	35.0%
State income taxes	3.3%	4.7%	4.3%
Research and development credits	(4.3)%	0.3%	0.9%
Stock-based compensation	(1.8)%	(1.0)%	(0.7)%
Change in valuation allowance	(28.1)%	(5.6)%	0.0%
State rate change	(2.1)%	0.6%	(0.0)%
Removal of net operating loss and research and development tax credits	0.0%	(32.4)%	(37.8)%
Other, net	<u>(2.0)%</u>	<u>(1.6)%</u>	<u>(1.7)%</u>
	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

At December 31, 2013, the Company had federal and state net operating loss carryforwards of approximately \$392,129,000 and \$387,589,000, respectively. The federal and state tax loss carryforwards will

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

begin to expire in 2024 and 2014, respectively, unless previously utilized. The Company also had federal research and development tax credit carryforwards of approximately \$4,140,000 which will begin expiring in 2025 unless previously utilized, and state research and development tax credit carryforwards of approximately \$2,524,000 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.

We recognize the impact of an uncertain income tax position on our income tax return at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

Following is a tabular reconciliation of the unrecognized tax benefit activity for the two years ended December 31, 2013 (excluding interest and penalties, in thousands):

Beginning balance, January 1, 2012	\$ —
Additions based on tax positions related to the current year	—
Reductions due to tax positions that reversed in the current year and completion of research and development study	\$ —
Ending balance December 31, 2012	—
Additions based on tax positions related to the current year	3,756
Reductions due to tax positions that reversed in the current year and completion of research and development study	—
Ending balance December 31, 2013	<u>\$3,756</u>

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 2013, 2012 and 2011, 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, 2013 and 2012 are as follows (in thousands, except per share data):

	Fiscal Year 2013 Quarters				Total
	1st ⁽³⁾	2nd	3rd	4th ⁽⁴⁾	
Revenues	\$23,612	\$ 24,674	\$28,957	\$35,313	\$112,556
Gross profit ⁽¹⁾	\$15,445	\$ 16,380	\$18,993	\$23,765	\$ 74,583
Net loss	\$ (1,363)	\$(11,875)	\$ (6,938)	\$ (4,118)	\$ (24,294)
Basic and diluted net loss per share ⁽²⁾	\$ (0.02)	\$ (0.14)	\$ (0.08)	\$ (0.05)	\$ (0.28)

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

	Fiscal Year 2012 Quarters				Total
	1st ⁽⁵⁾	2nd	3rd	4th ⁽⁶⁾	
Revenues	\$ 8,004	\$ 11,108	\$ 13,898	\$ 17,174	\$ 50,184
Gross profit ⁽¹⁾	\$ 3,758	\$ 5,352	\$ 7,822	\$ 9,996	\$ 26,928
Net loss	\$(22,673)	\$(20,989)	\$(15,890)	\$(21,421)	\$(80,973)
Basic and diluted net loss per share ⁽²⁾	\$ (0.27)	\$ (0.25)	\$ (0.19)	\$ (0.25)	\$ (0.95)

⁽¹⁾ Determined by subtracting cost of sales from net revenue.

⁽²⁾ 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.

⁽³⁾ During the first quarter of 2013, the Company recognized \$2,616 of previously deferred revenue and related cost of sales of \$919. Further, it recorded a gain of \$7,654 on the sale of its Incline option and preferred shares.

⁽⁴⁾ During the fourth quarter of 2013, the Company recognized \$2,027 of license revenue under its data license agreement with Terumo Corporation, related to their first commercial sale of its IV acetaminophen product in Japan.

⁽⁵⁾ During the first quarter of 2012, the Company recorded a charge of \$163 to write-down the value of certain inventory.

⁽⁶⁾ During the fourth quarter of 2012, the Company recorded charges of \$6,973 to impair certain manufacturing equipment and construction-in-process to their fair values and, a related asset retirement obligation impairment charge of \$750 for the removal of the equipment. Additionally, the Company recorded a loss on the sale of one of its construction-in-process assets of \$858 and a charge of \$290 to accrue for inventory destruction costs.

16. Subsequent Events

Agreement and Plan of Merger with Mallinckrodt plc

On February 10, 2014, the Company entered into an agreement and plan of merger (“Merger Agreement”) with Mallinckrodt plc (“Parent”) and Madison Merger Sub, Inc., a wholly owned indirect subsidiary of Parent (“Merger Sub”), pursuant to which, and on the terms and subject to the conditions thereof, among other things, Merger Sub commenced a tender offer (“Offer”) on February 19, 2014 to acquire all of the outstanding shares of common stock of the Company at a purchase price of \$14.00 per share in cash, without interest (the “Offer Price”). The Merger Agreement includes a remedy of specific performance and is not subject to a financing condition.

The obligation of Merger Sub to purchase the shares of common stock of the Company validly tendered pursuant to the Offer is subject to the satisfaction or waiver of a number of conditions set forth in the Merger Agreement, including (1) that there shall have been validly tendered and not validly withdrawn a number of shares of common stock of the Company that, when added to the shares then owned by Parent and its subsidiaries, represents one more than 50% of the total number of shares of common stock of the Company outstanding at the time of the expiration of the Offer, (2) the expiration or termination of applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (3) the accuracy of the representations and warranties and compliance with covenants contained in the Merger Agreement, (4) the absence of any law, order, injunction or decree by any government, court or governmental entity that would make illegal or otherwise prohibit the Offer or the Merger, (5) there not having been a material adverse effect with respect to the Company, (6) the delivery of certain audited and unaudited financial statements, and (7) other customary conditions.

CADENCE PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—Continued

The Merger Agreement contains certain termination rights in favor of each the Company and Parent, including under certain circumstances, the requirement for the Company to pay to Parent a termination fee of approximately \$20,200,000, or approximately 1.5% of the Offer Price. The Company has also agreed (1) to cease any existing, and agreed not to solicit or initiate any additional, discussions with third parties regarding other proposals to acquire the Company and (2) to certain restrictions on its ability to respond to such proposals, subject to fulfillment of certain fiduciary requirements of the board of directors of the Company.

Following the completion of the Offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into the Company, with the Company surviving as an indirect wholly owned subsidiary of Parent, pursuant to the procedure provided for under Section 251(h) of the Delaware General Corporation Law without any stockholder approvals (the “Merger”). At the effective time of the Merger (the “Effective Time”), by virtue of the Merger and without any action on the part of the holders of any shares of common stock of the Company, each outstanding share of common stock of the Company, other than any shares owned by Parent, Merger Sub or any wholly owned subsidiary of Parent or held in the treasury of the Company, or any stockholders who are entitled to and who properly exercise appraisal rights under Delaware law, will be canceled and converted into the right to receive an amount in cash equal to the Offer Price. In addition, (1) effective as of immediately prior to the Effective Time, each outstanding Company stock option will fully vest and automatically be canceled and terminated as of the Effective Time and the holder thereof will be entitled to receive an amount in cash, without interest and less the amount of any tax withholding, equal to the product of (a) the number of shares of common stock of the Company underlying such option multiplied by (b) the excess, if any, of the Offer Price over the exercise price per share of such option, (2) effective as of immediately prior to the Effective Time, each outstanding Company restricted stock unit, other than any Company restricted stock unit issued or awarded on or after January 1, 2014 (collectively, the “Specified Restricted Stock Units”), will fully vest and the restrictions thereon will lapse, and each such restricted stock unit will be canceled and converted into the right to receive an amount in cash, without interest and less the amount of any tax withholding, equal to the product of (a) the Offer Price multiplied by (b) the number of shares of common stock of the Company underlying such restricted stock unit, and (3) at the Effective Time, each outstanding Specified Restricted Stock Unit will be canceled and converted into an award (a “Converted Award”) representing the right to receive an amount in cash equal to the product of (a) the Offer Price multiplied by (b) the number of shares of Common Stock of the Company underlying such Specified Restricted Stock Unit. Each Converted Award shall continue to vest and be settled in cash in accordance with the terms of the applicable Specified Restricted Stock Unit award agreement, subject to accelerated vesting under certain circumstances, including in the event of the holder’s death or disability or an involuntary termination of employment that would otherwise qualify the holder to severance under any employment or severance plan or agreement to which the holder is a party or in which the holder is eligible to participate as of the date of grant. The foregoing treatment of the Specified Restricted Stock Unit Awards will supersede any more favorable vesting provisions in the Company’s equity plan or any employment or severance plan or agreement to which the holder is a party or in which the holder is eligible to participate (including the executive employment agreements).

The Merger Agreement contains customary representations, warranties and covenants, including covenants obligating the Company to continue to conduct its business in the ordinary course and to cooperate in seeking regulatory approvals.

The board of directors of the Company has unanimously (1) determined that the Merger Agreement and the transactions contemplated thereby are advisable and fair to, and in the best interests of, the Company’s stockholders, (2) approved and declared advisable the Merger Agreement and the transactions contemplated thereby and (3) resolved to recommend acceptance of the Offer by the Company’s stockholders. The board of

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directors of Parent has also unanimously approved the transaction. The Company expects to complete the Merger in mid to late March 2014, subject to the satisfaction of the closing conditions.

Exercise of Warrants

In January and February 2014, warrants to purchase an aggregate of 5,909,457 shares of the Company's common stock were exercised on a net exercise basis, which resulted in the issuance of a total of 2,454,472 shares of the Company's common stock. As of February 28, 2014, warrants to purchase an aggregate of 137,620 shares of the Company's common stock remained outstanding with an average exercise price of \$7.08 per share.

Schedule II
CADENCE PHARMACEUTICALS, INC.
Valuation and Qualifying Accounts
For the Years ended December 31, 2013, 2012 and 2011
(in thousands)

	<u>Allowance for doubtful accounts</u>	<u>Allowance for cash discounts, chargebacks, and wholesaler fees</u>
Balance at December 31, 2010	\$ —	\$ —
Additions	—	451
Deductions	—	(372)
Balance at December 31, 2011	—	79
Additions	56	1,912
Deductions	—	(1,766)
Balance at December 31, 2012	56	225
Additions	3	4,489
Deductions	(40)	(4,279)
Balance at December 31, 2013	<u>\$ 19</u>	<u>\$ 435</u>

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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, with the exception of the change discussed below, there were no other significant changes to our internal control over financial reporting during the year or quarter ended December 31, 2013, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Changes in internal control over financial reporting. As of January 1, 2013, we began to recognize revenue and estimate returns on sales of our product to wholesale customers. Prior to this time, we deferred the recognition of revenue until the time that the product had been sold by the wholesaler to a hospital or other end-user customer because the lack of historical product return data did not allow us to reasonably estimate returns on sales to the wholesalers. However, based upon product return history gathered since the commercial launch of our product in January 2011, we determined that we had sufficient data to reasonably estimate a return rate as of January 1, 2013. As a result, we changed our product return estimate and are now recognizing revenue on sales to wholesalers. The implementation of this change in our product return estimate resulted in the implementation of new controls, as well as changes to existing controls, systems and procedures that 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 generally 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 (1992) to evaluate the effectiveness of our internal control over financial reporting. Management's

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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, 2013, 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, 2013 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, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (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, 2013, 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, 2013 and 2012, and the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2013 of Cadence Pharmaceuticals, Inc. and our report dated February 28, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2014

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, 2013, 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, 2013, 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, 2013, 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, 2013, 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, 2013, 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 as follows:

Report of Independent Registered Public Accounting Firm	<u>Page</u> 77
Balance Sheets at December 31, 2013 and 2012	78
Statements of Operations for the years ended December 31, 2013, 2012 and 2011	79
Statements of Comprehensive Loss for the years ended December 31, 2013, 2012 and 2011	80
Statements of Stockholders' Equity for the years ended December 31, 2013, 2012 and 2011	81
Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011	82
Notes to Financial Statements	83

(2) *Financial Statements Schedules*. The following financial statement schedule of Cadence Pharmaceuticals, Inc., required to be filed pursuant to Part IV, Item 15 of this Annual Report on Form 10-K, is included as follows:

Schedule II –Valuation and Qualifying Accounts	<u>Page</u> 113
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(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>
2.1	Agreement and Plan of Merger, dated as of February 10, 2014, by and among Mallinckrodt plc, Madison Merger Sub, Inc. and the Company, incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 11, 2014
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	Certificate of Amendment of Amended and Restated Certificate of Incorporation 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 June 15, 2012
3.3 [±]	Amended and Restated Bylaws of the Company, as amended on December 14, 2007, and February 10, 2014
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

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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
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
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
4.10	Form of Warrant to Purchase Stock issued on December 5, 2012, incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 6, 2012
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 November 21, 2013, 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 November 26, 2013
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. 333-171396) as filed with the SEC on December 23, 2010

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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
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#	2013 Corporate Bonus Plan, incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K (File No. 001-33103) for the year ended December 31, 2012 as filed with the SEC on March 8, 2013
10.11#	2014 Corporate Bonus 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 November 26, 2013
10.12#	Executive Severance Plan, incorporated herein by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K (File No. 001-33103) for the year ended December 31, 2012 as filed with the SEC on March 8, 2013
10.13	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
10.14	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
10.15	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
10.16	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
10.17	First Amendment to Lease dated September 29, 2006 by and between the Company and Prentiss/Collins Del Mar Heights LLC, incorporated herein by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K (File No. 001-33103) for the year ended December 31, 2011 as filed with the SEC on March 13, 2012
10.18	Second Amendment to Lease dated December 8, 2011 by and among the Company and PR II High Bluffs LLC and Collins Corporate Center Partners, LLC, incorporated herein by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K (File No. 001-33103) for the year ended December 31, 2011 as filed with the SEC on March 13, 2012
10.19	Third Amendment to Lease dated September 24, 2013 by and among the Company and PR II High Bluffs LLC and Collins Corporate Center Partners, LLC, 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 27, 2013

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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.20†	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
10.21†	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
10.22†	Supply Agreement dated December 1, 2010 by and between the Company and Lawrence Laboratories, 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
10.23†	Amended and Restated Supply Agreement dated February 22, 2013 by and between the Company and Lawrence Laboratories, 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 28, 2013
10.24†	Amended and Restated Development and Supply Agreement dated January 28, 2011 by and between the Company and Baxter Healthcare 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 February 2, 2011
10.25†	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
10.26	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
10.27	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
10.28	First Amendment to Second Amended and Restated Loan and Security Agreement, dated December 5, 2012, by and among the Company and Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation, incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 6, 2012
10.29†	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
10.30	Waiver, Consent and Option Termination Agreement dated December 11, 2012 by and between the Company and Incline Therapeutics, Inc., incorporated herein by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K (File No. 001-33103) for the year ended December 31, 2012 as filed with the SEC on March 8, 2013

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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.31 [†]	Settlement Agreement dated November 27, 2012 by and between the Company and SCR Pharmatop and Paddock Laboratories, LLC and Perrigo Company, incorporated herein by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K (File No. 001-33103) for the year ended December 31, 2012 as filed with the SEC on March 8, 2013
10.32 [†]	License Agreement dated November 27, 2012 by and between the Company and SCR Pharmatop and Paddock Laboratories, LLC and Perrigo Company, 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, 2012 as filed with the SEC on March 8, 2013
10.33 [†]	Settlement Agreement dated January 28, 2014 by and between the Company and SCR Pharmatop and Sandoz Inc., Sandoz AG, Neogen International N.V. and APC Pharmaceuticals, LLC, including the Binding Term Sheet dated January 28, 2014
23.1 [±]	Consent of Independent Registered Public Accounting Firm
31.1 [±]	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2 [±]	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1 [±]	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002
99.1	Tender and Support Agreement, dated February 10, 2014, by and among Mallinckrodt plc, Madison Merger Sub, Inc. and certain stockholders of the Company, incorporated herein by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K (File No. 333-138226) as filed with the SEC on February 11, 2014
101.INS [±]	XBRL Instance Document
101.SCH [±]	XBRL Taxonomy Extension Schema Document
101.CAL [±]	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF [±]	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB [±]	XBRL Taxonomy Extension Label Linkbase Document
101.PRE [±]	XBRL Taxonomy Extension Presentation Linkbase Document

[±] Included in this Report.

Indicates management contract or compensatory plan.

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

**AMENDED AND RESTATED
BYLAWS
OF
CADENCE PHARMACEUTICALS, INC.**

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**AMENDED AND RESTATED
BYLAWS
OF
CADENCE PHARMACEUTICALS, INC.**

**ARTICLE I.
OFFICES**

Section 1. REGISTERED OFFICES. The registered office shall be in the City of Wilmington, County of New Castle, State of Delaware.

Section 2. OTHER OFFICES. The corporation may also have offices at such other places both within and without the State of Delaware as the Board of Directors (the "Board") may from time to time determine or the business of the corporation may require.

**ARTICLE II.
MEETINGS OF STOCKHOLDERS**

Section 1. PLACE OF MEETINGS. Meetings of stockholders shall be held at any place within or outside the State of Delaware designated by the Board. In the absence of any such designation, stockholders' meetings shall be held at the principal executive office of the corporation.

Section 2. ANNUAL MEETING OF STOCKHOLDERS. The annual meeting of stockholders shall be held each year on a date and time designated by the Board. At each annual meeting directors shall be elected, and any other proper business may be transacted.

Section 3. QUORUM; ADJOURNED MEETINGS AND NOTICE THEREOF. A majority of the stock issued and outstanding and entitled to vote at any meeting of stockholders, the holders of which are present in person or represented by proxy, shall constitute a quorum for the transaction of business except as otherwise provided by law, by the Certificate of Incorporation or by these Bylaws. A quorum, once established, shall not be broken by the withdrawal of enough votes to leave less than a quorum, and the votes present may continue to transact business until adjournment. If, however, such quorum shall not be present or represented at any meeting of the stockholders, a majority of the voting stock represented in person or by proxy may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present or represented. At such adjourned meeting at which a quorum shall be present or represented, any business may be transacted which might have been transacted at the meeting as originally notified. If the adjournment is for more than thirty days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote thereat.

Section 4. VOTING. When a quorum is present at any meeting, in all matters other than the election of directors, the vote of the holders of a majority of the stock having voting power present in person or represented by proxy and entitled to vote on a particular question shall decide such question brought before such meeting, unless the question is one upon which by express provision of the statutes, the Certificate of Incorporation or these Bylaws, a different vote is required in which case such express provision shall govern and control the decision of such question. Directors shall be elected by a plurality of the votes of the stock present in person or represented by proxy at the meeting and entitled to vote on the election of directors.

Section 5. PROXIES. At each meeting of the stockholders, each stockholder having the right to vote may vote in person or may authorize another person or persons to act for him or her by proxy appointed by an instrument in writing subscribed by such stockholder and bearing a date not more than three years prior to said meeting, unless said instrument provides for a longer period. All proxies must be filed with the Secretary of the corporation at the beginning of each meeting in order to be counted in any vote at the meeting. Each stockholder shall have one vote for each share of stock having voting power, registered in his name on the books of the corporation on the record date set by the Board as provided in Article II, Section 8 hereof.

Section 6. SPECIAL MEETINGS. Special meetings of the stockholders, for any purpose or purposes, unless otherwise prescribed by statute or by the Certificate of Incorporation, may be called by the Chairman of the Board or the President and shall be called by the President or the Secretary at the request in writing of a majority of the members of the Board. Business transacted at any special meeting of stockholders shall be limited to the purposes stated in the notice.

Section 7. NOTICE OF STOCKHOLDERS' MEETINGS. Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given, which notice shall state the place, date and hour of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. The written notice of any meeting shall be given to each stockholder entitled to vote at such meeting not less than ten nor more than sixty days before the date of the meeting. If mailed, notice is deemed given when deposited in the United States mail, postage prepaid, directed to the stockholder at his address as it appears on the records of the corporation.

Section 8. FIXING DATE FOR DETERMINATION OF STOCKHOLDERS OF RECORD. In order that the corporation may determine the stockholders entitled to notice of, or to vote at, any meeting of stockholders or any adjournment thereof, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date: (a) in the case of determination of stockholders entitled to vote at any meeting of stockholders or adjournment thereof, shall, unless otherwise required by law, not be more than sixty nor less than ten days before the date of such meeting; and (b) in the case of any other action, shall not be more than sixty days prior to such other action. If no record date is fixed: (i) the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held; and (ii) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto. A determination of stockholders of record entitled to notice of, or to vote at, a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for the adjourned meeting.

Section 9. NOTICE OF STOCKHOLDER BUSINESS AND NOMINATIONS.

(a) Nominations of persons for election to the Board of the corporation and the proposal of business to be considered by the stockholders may be made at an annual meeting of stockholders (i) pursuant to the corporation's notice of meeting (or any supplement thereto), (ii) by or at the direction of the Board or (iii) by any stockholder of the corporation who was a stockholder of

record at the time notice provided for in this Section 9 is given to the Secretary of the corporation, who is entitled to vote at the meeting and who complies with the notice procedures in this Section 9.

(b) For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of paragraph (a) of this Section 9, the stockholder must have given timely notice thereof in writing to the Secretary of the corporation, and any such proposed business other than the nominations of persons for election to the Board must constitute a proper matter for stockholder action. To be timely, a stockholder's notice shall be delivered to the Secretary at the principal executive offices of the corporation not later than the close of business on the ninetieth day nor earlier than the close of business on the one hundred twentieth day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is more than thirty days before or more than sixty days after such anniversary date, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the one hundred twentieth day prior to such annual meeting and not later than the close of business on the later of the ninetieth day prior to such annual meeting or the tenth day following the earlier of (i) the day on which notice of the meeting was mailed or (ii) the date public announcement of the date of such meeting is first made by the corporation. In no event shall the public announcement of an adjournment or postponement of an annual meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. Such stockholder's notice shall set forth: (A) as to each person whom the stockholder proposes to nominate for election or re-election as a director, all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 14a-101 thereunder (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected); (B) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend the Bylaws, the language of the proposed amendment), the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the nomination or proposal is made; and (C) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made, (I) the name and address of such stockholder and of such beneficial owner, as they appear on the corporation's books, (II) the class and number of shares of capital stock of the corporation which are owned beneficially and of record by such stockholder and such beneficial owner, (III) a representation that the stockholder is a holder of record of stock of the corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business or nomination and (IV) a representation whether the stockholder or the beneficial owner, if any, intends or is part of a group which intends (y) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the corporation's outstanding capital stock required to approve or adopt the proposal or elect the nominee and/or (z) otherwise to solicit proxies from stockholders in support of such proposal or nomination. The foregoing notice requirements shall be deemed satisfied by a stockholder if the stockholder has notified the corporation of his or her intention to present a proposal at an annual meeting in compliance with Rule 14a-8 (or any successor thereof) promulgated under the Exchange Act and such stockholder's proposal has been included in a proxy statement that has been prepared by the corporation to solicit proxies for such annual meeting. The corporation may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as a director of the corporation.

(c) Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the corporation's notice of meeting. Nominations of persons for election to the Board may be made at a special meeting of stockholders at which directors are to be elected pursuant to the corporation's notice of meeting (i) by or at the direction of the Board or (ii) provided that the Board has determined that directors shall be elected at such meeting, by any stockholder of the corporation who is a stockholder of record at the time the notice provided for in this Section 9 is delivered to the Secretary of the corporation, who is entitled to vote at the meeting and who complies with the notice procedures set forth in this Section 9. In the event the corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board, any such stockholder entitled to vote in such election of directors may nominate a person or persons (as the case may be) for election to such position(s) as specified in the corporation's notice of meeting, if the stockholder's notice required by paragraph (b) of this Section 9 shall be delivered to the Secretary at the principal executive offices of the corporation not earlier than the close of business on the one hundred twentieth day prior to such special meeting and not later than the close of business on the later of (i) the ninetieth day prior to such special meeting or (ii) the tenth day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board to be elected at such meeting. In no event shall the public announcement of an adjournment or postponement of a special meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(d) (i) Only such persons who are nominated in accordance with the procedures set forth in this Section 9 shall be eligible to be elected at an annual or special meeting of stockholders of the corporation to serve as directors, and only such business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 9. Except as otherwise provided by law, the chairman of the meeting shall have the power and duty (A) to determine whether a nomination or any business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with the procedures set forth in this Section 9 (including whether the stockholder or beneficial owner, if any, on whose behalf the nomination or proposal is made solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies in support of such stockholder's nominee or proposal in compliance with such stockholder's representation as required by paragraph (b) of this Section 9) and (B) if any proposed nomination or business was not made or proposed in compliance with this Section 9, to declare that such nomination shall be disregarded or that such proposed business shall not be transacted. Notwithstanding the foregoing provisions of this Section 9, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual or special meeting of stockholders of the corporation to present a nomination or business, such nomination shall be disregarded and such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the corporation.

(ii) For purposes of this Section 9, "public announcement" shall include disclosure in a press release reported by PRNewswire, Business Wire, the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act.

(iii) Notwithstanding the foregoing provisions of this Section 9, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations promulgated thereunder with respect to the matters set forth in this Section 9. Nothing in this Section 9 shall be deemed to affect any rights (A) of stockholders to request inclusion of proposals in the

corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act or (B) of the holders of any series of preferred stock of the corporation to elect directors pursuant to any applicable provisions of the Certificate of Incorporation.

Section 10. MAINTENANCE AND INSPECTION OF STOCKHOLDER LIST. The officer who has charge of the stock ledger of the corporation shall prepare and make, at least ten days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten days prior to the meeting, either at a place within the city where the meeting is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present.

Section 11. STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING. Unless otherwise provided in the Certificate of Incorporation, any action required to be taken at any annual or special meeting of stockholders of the corporation, or any action which may be taken at any annual or special meeting of such stockholders, may not be taken without a meeting.

ARTICLE III. DIRECTORS

Section 1. THE NUMBER OF DIRECTORS. The number of directors which shall constitute the whole Board shall be not less than three nor more than fifteen. The actual number of directors shall be fixed from time to time solely by resolution adopted by the affirmative vote of a majority of the directors. The directors need not be stockholders. The directors shall be elected at the annual meeting of the stockholders, except as provided in Section 2 of this Article, and each director elected shall hold office until his successor is elected and qualified; provided, however, that unless otherwise restricted by the Certificate of Incorporation or by law, any director or the entire Board may be removed, for cause, from the Board at any meeting of stockholders by not less than 66 2/3% of the outstanding stock of the Corporation.

Section 2. VACANCIES. Vacancies on the Board by reason of death, resignation, retirement, disqualification, removal from office or otherwise, and newly created directorships resulting from any increase in the authorized number of directors may be filled solely by a vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director, and each director so elected shall hold office for a term that shall coincide with the remaining term of the class to which such director shall have been elected. If there are no directors in office, then an election of directors may be held in the manner provided by statute. If, at the time of filling any vacancy or any newly created directorship, the directors then in office shall constitute less than a majority of the whole Board (as constituted immediately prior to any such increase), the Court of Chancery may, upon application of any stockholder or stockholders holding at least ten percent of the total number of the shares at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office.

Section 3. **POWERS.** The property and business of the corporation shall be managed by or under the direction of its Board. In addition to the powers and authorities by these Bylaws expressly conferred upon them, the Board may exercise all such powers of the corporation and do all such lawful acts and things as are not by statute, by the Certificate of Incorporation or by these Bylaws directed or required to be exercised or done by the stockholders.

Section 4. **PLACE OF DIRECTORS' MEETINGS.** The directors may hold their meetings, have one or more offices and keep the books of the corporation outside of the State of Delaware.

Section 5. **REGULAR MEETINGS.** Regular meetings of the Board may be held without notice at such time and place as shall from time to time be determined by the Board.

Section 6. **SPECIAL MEETINGS.** Special meetings of the Board may be called by the Chairman of the Board or the President on forty-eight hours' notice to each director, either personally, by mail, electronic mail or by telegram; special meetings shall be called by the President or the Secretary in like manner and on like notice on the written request of two directors, unless the Board consists of only one director, in which case special meetings shall be called by the President or Secretary in like manner or on like notice on the written request of the sole director.

Section 7. **QUORUM.** At all meetings of the Board a majority of the authorized number of directors shall be necessary and sufficient to constitute a quorum for the transaction of business, and the vote of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board, except as may be otherwise specifically provided by statute, by the Certificate of Incorporation or by these Bylaws. If a quorum shall not be present at any meeting of the Board, the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present. If only one director is authorized, such sole director shall constitute a quorum.

Section 8. **ACTION WITHOUT MEETING.** Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting, if all members of the Board or committee, as the case may be, consent thereto in writing, and the writing or writings are filed with the minutes of proceedings of the Board or committee.

Section 9. TELEPHONIC MEETINGS. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, members of the Board, or any committee designated by the Board, may participate in a meeting of the Board, or any committee, by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at such meeting.

Section 10. COMMITTEES OF DIRECTORS. The Board may, by resolution passed by a majority of the whole Board, designate one or more committees, each such committee to consist of one or more of the directors of the corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he, she or they constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the corporation and may authorize the seal of the corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to amending the Certificate of Incorporation, adopting an agreement of merger or consolidation, recommending to the stockholders the sale, lease or exchange of all or substantially all of the corporation's property and assets, recommending to the stockholders a dissolution of the corporation or a revocation of a dissolution, or amending the Bylaws of the corporation; and, unless the resolution or the Certificate of Incorporation expressly so provide, no such committee shall have the power or authority to declare a dividend or to authorize the issuance of stock.

Section 11. MINUTES OF COMMITTEE MEETINGS. Each committee shall keep regular minutes of its meetings and report the same to the Board when required.

Section 12. COMPENSATION OF DIRECTORS. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, the Board shall have the authority to fix the compensation of directors. The directors may be paid their expenses, if any, of attendance at each meeting of the Board and may be paid a fixed sum for attendance at each meeting of the Board or a stated salary as director. No such payment shall preclude any director from serving the corporation in any other capacity and receiving compensation therefor. Members of special or standing committees may be allowed like compensation for attending committee meetings.

ARTICLE IV. OFFICERS

Section 1. OFFICERS. The officers of this corporation shall be chosen by the Board and shall include a President, a Secretary and a Chief Financial Officer or Treasurer. The corporation may also have at the discretion of the Board such other officers as are desired, including one or more Vice Presidents, one or more Assistant Secretaries and Assistant Treasurers and such other officers as may be appointed in accordance with the provisions of Section 3 hereof. In the event there are two or more Vice Presidents, then one or more may be designated as Executive Vice President, Senior Vice President or other similar or dissimilar title. At the time of the election of officers, the directors may by resolution determine the order of their rank. Any number of offices may be held by the same person, unless the Certificate of Incorporation or these Bylaws otherwise provide.

Section 2. ELECTION OF OFFICERS. The Board, at its first meeting after each annual meeting of stockholders, shall choose the officers of the corporation.

Section 3. SUBORDINATE OFFICERS. The Board may appoint such other officers and agents as it shall deem necessary who shall hold their offices for such terms and shall exercise such powers and perform such duties as shall be determined from time to time by the Board.

Section 4. COMPENSATION OF OFFICERS. The salaries of all officers and agents of the corporation shall be fixed by the Board.

Section 5. TERM OF OFFICE; REMOVAL AND VACANCIES. The officers of the corporation shall hold office until their successors are chosen and qualify in their stead. Any officer elected or appointed by the Board may be removed at any time by the affirmative vote of a majority of the Board. If the office of any officer or officers becomes vacant for any reason, the vacancy shall be filled by the Board.

Section 6. POWERS AND DUTIES OF OFFICERS. The officers of the corporation shall have such powers and duties in the management of the corporation as may be prescribed in a resolution by the Board and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board.

**ARTICLE V.
INDEMNIFICATION OF EMPLOYEES AND AGENTS**

The corporation may indemnify every person who is or was a party or is or was threatened to be made a party to any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was an employee or agent of the corporation or, while an employee or agent of the corporation, is or was serving at the request of the corporation as an employee or agent or trustee of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against expenses (including counsel fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action, suit or proceeding, to the extent permitted by applicable law.

**ARTICLE VI.
CERTIFICATES OF STOCK**

Section 1. CERTIFICATES. Every holder of stock of the corporation shall be entitled to have a certificate signed by, or in the name of the corporation by, the President or a Vice President and by the Secretary or an Assistant Secretary, or the Treasurer or an Assistant Treasurer of the corporation, certifying the number of shares represented by the certificate owned by such stockholder in the corporation.

Section 2. SIGNATURES ON CERTIFICATES. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if he or she were such officer, transfer agent or registrar at the date of issue.

Section 3. STATEMENT OF STOCK RIGHTS, PREFERENCES, PRIVILEGES. If the corporation shall be authorized to issue more than one class of stock or more than one series of any class, the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualification, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate which the corporation shall issue to represent such class or series of stock, provided that, except as otherwise provided in section 202 of the General Corporation Law of Delaware, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate which the corporation shall issue to represent such class or series of stock, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Section 4. LOST CERTIFICATES. The Board may direct a new certificate or certificates to be issued in place of any certificate or certificates theretofore issued by the corporation alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed. When authorizing such issue of a new certificate or certificates, the Board may, in its discretion and as a condition precedent to the issuance thereof, require the owner of such lost, stolen or destroyed certificate or certificates, or his legal representative, to advertise the same in such manner as it shall require and/or to give the corporation a bond in such sum as it may direct as indemnity against any claim that may be made against the corporation with respect to the certificate alleged to have been lost, stolen or destroyed.

Section 5. TRANSFERS OF STOCK. Upon surrender to the corporation, or the transfer agent of the corporation, of a certificate for shares duly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer, it shall be the duty of the corporation to issue a new certificate to the person entitled thereto, cancel the old certificate and record the transaction upon its books.

Section 6. REGISTERED STOCKHOLDERS. The corporation shall be entitled to treat the holder of record of any share or shares of stock as the holder in fact thereof and accordingly shall not be bound to recognize any equitable or other claim or interest in such share on the part of any other person, whether or not it shall have express or other notice thereof, except as expressly provided by the laws of the State of Delaware.

ARTICLE VII. GENERAL PROVISIONS

Section 1. CHECKS. All checks or demands for money and notes of the corporation shall be signed by such officer or officers as the Board may from time to time designate.

Section 2. FISCAL YEAR. The fiscal year of the corporation shall be fixed by resolution of the Board.

Section 3. CORPORATE SEAL. The corporate seal shall have inscribed thereon the name of the corporation and shall be in such form as may be approved from time to time by the Board.

Section 4. MANNER OF GIVING NOTICE. Whenever, under the law, the Certificate of Incorporation or these Bylaws, notice is required to be given to any director or stockholder, it shall not be construed to mean personal notice, but such notice may be given in writing, by mail, addressed to such director or stockholder, at his address as it appears on the records of the corporation, with postage thereon prepaid, and such notice shall be deemed to be given at the time when the same shall be deposited in the United States mail. Notice to directors may also be given by telegram, telecopier or other means of communication permitted by law.

Section 5. WAIVER OF NOTICE. Whenever any notice is required to be given under the law, the Certificate of Incorporation or these Bylaws, a waiver thereof via electronic mail or in writing, signed by the person or persons entitled to said notice, whether before or after the time stated therein, shall be deemed equivalent thereto. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at nor the purpose of any regular or special meeting of the stockholders, directors or members of a committee of directors need be specified in any written waiver of notice.

**ARTICLE VIII.
AMENDMENTS**

These Bylaws may be altered, amended or repealed or new Bylaws may be adopted by the stockholders or by the Board in accordance with the terms of the Certificate of Incorporation. If the power to adopt, amend or repeal Bylaws is conferred upon the Board by the Certificate of Incorporation, it shall not divest or limit the power of the stockholders to adopt, amend or repeal Bylaws.

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**AMENDMENT OF AMENDED AND RESTATED BYLAWS
OF
CADENCE PHARMACEUTICALS, INC.
DECEMBER 14, 2007**

The Amended and Restated Bylaws of Cadence Pharmaceuticals, Inc. are amended as follows:

1. Article VI, Section 1 of the Amended and Restated Bylaws is hereby amended and restated in its entirety as follows:

Section 1. FORM AND EXECUTION OF CERTIFICATES.

Shares of the corporation's stock may be certificated or uncertificated, as provided under Delaware law. Certificates for the shares of stock of the corporation shall be in such form as is consistent with the Certificate of Incorporation and applicable law. Every holder of stock of the corporation shall be entitled to have a certificate signed by, or in the name of the corporation by, the President or a Vice President and by the Secretary or an Assistant Secretary, or the Treasurer or an Assistant Treasurer of the corporation, certifying the number of shares represented by the certificate owned by such stockholder in the corporation.

2. Article VI, Section 5 of the Amended and Restated Bylaws is hereby amended and restated in its entirety as follows:

Section 5. TRANSFERS OF STOCK.

Transfers of record of shares of stock of the corporation shall be made only upon its books by the holders thereof, in person or by attorney duly authorized, and, in the case of stock represented by a certificate, upon surrender to the corporation, or the transfer agent of the corporation of a certificate or certificates for shares duly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer for a like number of shares.

**SECOND AMENDMENT TO THE
AMENDED AND RESTATED BYLAWS OF
CADENCE PHARMACEUTICALS, INC.**

The Amended and Restated Bylaws of Cadence Pharmaceuticals, Inc. are hereby amended, effective as of February 10, 2014, to add the following new Section 6 to Article VII:

Section 6. FORUM FOR ADJUDICATION OF DISPUTES.

Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery (the "Chancery Court") of the State of Delaware (or, in the event that the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) shall be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the corporation, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the corporation to the corporation or the corporation's stockholders, (c) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or the Certificate of Incorporation or these Bylaws (as either may be amended from time to time), or (d) any action asserting a claim governed by the internal affairs doctrine.

SETTLEMENT AGREEMENT

This Settlement Agreement (including Exhibit A, this "Settlement Agreement") is made and entered into, as of January 28, 2014, by and between, on the one hand, Cadence Pharmaceuticals, Inc., a corporation organized under the laws of Delaware ("Cadence"), and SCR Pharmatop, a civil law partnership organized and existing under the laws of France ("Pharmatop" and, together with Cadence, the "Cadence Parties"), and, on the other hand, Sandoz Inc., a corporation organized under the laws of Colorado ("Sandoz Inc."), Sandoz AG, a corporation organized under the laws of Switzerland ("AG" and, together with Sandoz Inc., "Sandoz"), Neogen International N.V., organized under the laws of Belgium ("Neogen"), and APC Pharmaceuticals, LLC, a limited liability company organized under the laws of Delaware ("APC" and, together with Sandoz and Neogen, the "Sandoz Parties"). Each of the Cadence Parties and Sandoz Parties is referred to as a "Party" and, collectively, as the "Parties".

RECITALS

WHEREAS, Pharmatop owns, Cadence is the exclusive sub-licensee of, and the Cadence Parties have the right to enforce, U.S. Patent Nos. 6,028,222 (the "'222 Patent") and 6,992,218 (the "'218 Patent"), which are listed in the U.S. Food and Drug Administration's (the "US FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), in connection with approved New Drug Application ("NDA") No. 022450 for the drug formulation OFIRMEV® (injectable acetaminophen) 10 mg/mL, 100 mL vials (the "Cadence Product"), which product Cadence has sold or sells in the United States of America;

WHEREAS, Sandoz Inc., notified the Cadence Parties that it had submitted Abbreviated New Drug Application ("ANDA") No. [***] to the US FDA under Section 505(j)(2)(B) of the U.S. Food, Drug, and Cosmetic Act, seeking the US FDA's approval to manufacture, use and sell an injectable acetaminophen drug product in the United States of America as a generic version of the Cadence Product (the "Sandoz Product") prior to expiration of the '218 Patent and the '222 Patent as such ANDA may be amended or supplemented from time to time (the "Sandoz ANDA");

WHEREAS, the Cadence Parties commenced a civil action against Sandoz before the United States District Court for the Southern District of California (the "District Court"), *Cadence Pharmaceuticals, Inc. and SCR Pharmatop v. Sandoz Inc. et al.*, Case No. 13-cv-0278-DMS-MDD (S.D. Cal.), pending in the District Court, alleging, *inter alia*, that the filing of the Sandoz ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A) of the '218 Patent and the '222 Patent (the "Pending Litigation"); and

WHEREAS, the Parties are willing to settle the Pending Litigation on the terms set forth herein and in the Term Sheet (as defined below), in an effort to avoid further litigation and contain associated fees, costs, and expenses.

NOW, THEREFORE, in consideration of the mutual covenants set forth herein and in the Term Sheet, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

1. **Definitions.** All capitalized terms used, but not otherwise defined herein, shall have the meanings set forth in the Term Sheet. As used herein, the following capitalized terms shall have the meanings ascribed to them below:

“**Commercially Reasonable Efforts**” means the reasonable, diligent, and good-faith efforts as a Party would normally use to accomplish a similar objective under similar circumstances.

“**Execution Date**” means the date on which all the Parties have executed this Settlement Agreement and the Term Sheet.

“**Market**” means to offer for sale, sell, promote or distribute a product.

“**Pending Claims**” means any claim related to or arising out of preparation and submission of the Sandoz ANDA, known or unknown, suspected or unsuspected, asserted or unasserted, at law or in equity, that could have been, is or was asserted in, or could have been, is or was the subject matter of, the Pending Litigation.

“**Person**” means an individual, partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, governmental authority, or other entity of whatever nature.

“**Term Sheet**” means the Term Sheet, between the Parties hereto, attached to this Settlement Agreement as Exhibit B (the terms of which may be subsequently memorialized in a definitive agreement).

2. **Antitrust Review.**

(a) As soon as practicable and in no event later than [***] following the Execution Date, the Parties shall submit this Settlement Agreement and the Term Sheet to the appropriate personnel at the United States Federal Trade Commission and Antitrust Division of United States Department of Justice (the “**Agencies**”) for review under Section 1112 of the Medicare Prescription Drug Improvement and Modernization Act of 2003. Each Party shall notify the other Parties when it has submitted this Settlement Agreement to the Agencies.

(b) If, within [***] of receipt of this Settlement Agreement by the Agencies, any Agency objects to, responds to, or otherwise comments on such submission, or requests information concerning such submission, the Parties shall use Commercially Reasonable Efforts to address or resolve such objection, response or comment and respond to such request for information; *provided, however*, that such Commercially Reasonable Efforts shall not result in a material change to the rights and obligations of the Parties under this Settlement Agreement and the Term Sheet, except as the Parties may otherwise mutually agree in writing. Such Commercially Reasonable Efforts to address or resolve any such objection, response or comment or to respond to such request shall continue for a period of not more than [***] from when such objection, response or comment is first raised or such request is first made, unless the Parties mutually agree in writing to extend such [***] period. If, despite such Commercially Reasonable Efforts, either Party concludes that the Parties are unable to adequately address or resolve any such objection, response or comment, or to respond to such request for information during such

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

[***] period or agreed extension thereof, the Parties shall, unless they agree otherwise in writing, promptly reinstate the Pending Litigation. In the event of such reinstatement, the Parties shall use Commercially Reasonable Efforts to return the Parties to the position they were in before signing this Settlement Agreement; and the Sandoz Parties shall not challenge the applicability or reinstatement of the full balance of any stay of US FDA approval existing as of the Execution Date as to which the Sandoz ANDA would have been subject but for the execution of this Settlement Agreement and the Term Sheet. In the event of such reinstatement, none of the Sandoz Parties shall Market the Sandoz Product prior to the date on which any such stay existing as of the Execution Date would have expired but for the execution of the Settlement Documents (as defined below). Upon accomplishing such reinstatement, this Settlement Agreement and the Term Sheet shall terminate and shall be void *ab initio*.

3. Stipulation and Order of Dismissal.

(a) In consideration of the mutual benefits of entering into this Settlement Agreement, the Parties shall enter into and cause to be filed with the District Court, within [***] after the Execution Date, a stipulation and proposed order dismissing with prejudice all claims, defenses and counterclaims as between the Cadence Parties and the Sandoz Parties in the Pending Litigation, substantially in the form annexed hereto as Exhibit A (“Stipulation and Order of Dismissal With Prejudice”).

(b) If the District Court raises an objection to, or does not grant, the Stipulation and Order of Dismissal With Prejudice in substantially the same form as that annexed hereto as Exhibit A, the Parties shall confer in good faith and revise the Stipulation and Order of Dismissal With Prejudice consistent with the requirements of the District Court and this Settlement Agreement and the Term Sheet.

(c) The Parties agree that this Settlement Agreement and the Term Sheet (collectively, the “Settlement Documents”) shall become effective, and shall be binding on any such Party, on and as of the Execution Date.

4. Settlement and Release. From the Execution Date, the Parties agree as follows:

(a) The Cadence Parties, on behalf of themselves and their respective Affiliates, hereby release, acquit, and discharge the Sandoz Parties and their respective Affiliates from all Pending Claims. The foregoing release discharge covers all of such Pending Claims, from the beginning of time through and including the Execution Date.

(b) The Sandoz Parties, on behalf of themselves and their respective Affiliates, hereby release, acquit, and discharge the Cadence Parties and their respective Affiliates from all Pending Claims. The foregoing release covers all of such Pending Claims, from the beginning of time through and including the Execution Date.

5. Scope of Settlement and Release. Notwithstanding anything to the contrary elsewhere in Sections 3 and 4, nothing in this Settlement Agreement is intended to prevent or preclude any of the Parties (a) from participating in (including, without limitation, initiating) future proceedings that bear upon or relate to (i) the Parties’ respective obligations or rights under this Settlement Agreement and/or the Term Sheet, including, without limitation, post-Execution Date treatment or resolution of issues related to and/or the enforcement of this Settlement Agreement and/or the Term Sheet, or (ii) subject to the terms of the Term Sheet and the Definitive Agreement, claims that are unrelated to either the Pending Litigation or the Sandoz Product, or (b) from invoking the continuing jurisdiction of the District Court to enforce this Settlement Agreement and/or the Term Sheet.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

6. Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Parties as follows:

(a) that such Party has obtained the advice of legal counsel prior to such Party's execution and delivery of the Settlement Documents, and that such Party's execution and delivery of this Settlement Agreement containing the releases set forth above are made voluntarily, with full knowledge of their significance, and with the express intention of extinguishing all obligations;

(b) that such Party has the corporate, partnership or limited liability company power and authority to enter into the Settlement Documents and to perform its obligations hereunder and thereunder;

(c) the Settlement Documents have been duly authorized, executed and delivered and constitute the legal, valid, and binding obligations of such Party, enforceable in accordance with their terms;

(d) the execution, delivery, and performance of the Settlement Documents do not and will not violate or conflict with any provision of such Party's Certificate of Incorporation or bylaws, or other operating or partnership agreement, as applicable and in effect on the Execution Date;

(e) that the execution and delivery of the Settlement Documents and the performance by the Party of any of its obligations hereunder do not and will not conflict with or result in a breach of any other agreement to which it or any of its Affiliates is a party, any judgment of any court or governmental body applicable to the Party or its properties, or, to the Party's knowledge, any statute, decree, order, rule or regulation of any court or governmental authority applicable to the Party or its properties;

(f) that such Party: (i) has read the Settlement Documents, (ii) fully understands all the terms and conditions thereof and the meaning of each provision thereof (including specifically the releases and covenants contained herein), and (iii) has entered into the Settlement Documents of its own free will and volition, has been advised to consult counsel, has had the opportunity to consult with counsel concerning the Settlement Documents, and freely and voluntarily enters into them; and

(g) the Settlement Documents were negotiated by the Parties on an arm's-length basis, and nothing in the Settlement Documents shall be construed as establishing a special relationship of trust and confidence, fiduciary, partnership or joint venture relationship between the Parties.

(h) [***]

7. Acknowledgements, Settlement Agreements and Covenants. The Parties consent to the jurisdiction and venue of the District Court for the purposes of the settlement of the Pending Litigation and enforcement of the terms of the Settlement Documents. The Parties acknowledge and agree that any breach of the Term Sheet shall constitute a breach of this Settlement Agreement. Subject to the terms of the Term Sheet, the Sandoz Parties acknowledge and admit that, in the absence of the Term Sheet, the making, using, selling, offering for sale, or importing of the Sandoz Product would infringe the asserted claims of the '218 Patent and the '222 Patent, that the filing of the Sandoz ANDA No. [***] was a technical act of infringement with respect to the asserted claims of the '218 Patent and the '222 Patent, and that the asserted claims of the '218 Patent and the '222 Patent are valid and enforceable as against the Sandoz Product and Sandoz ANDA No. [***] only. For purposes of clarity, nothing herein (i) prevents the Sandoz Parties from challenging the infringement, enforceability or validity of the '218 Patent or the '222 Patent in judicial proceedings in connection with any product other than the Sandoz Product or any ANDA other than the Sandoz ANDA, including but not limited to the filing of any "Paragraph IV Certification" under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (as amended or replaced) to the '218 Patent or the '222 Patent, the filing of any declaratory judgment action against the '218 Patent or the '222 Patent, and engaging in the defense of, or in response to, any assertion of infringement of the '218 Patent or the '222 Patent, in each case in connection with a product other than the Sandoz Product or Sandoz ANDA, or (ii) prevents assertion in the future of the '218 Patent or the '222 Patent against any product other than the Sandoz Product or Sandoz ANDA.

From and after the Execution Date, each of the Sandoz Parties agrees, on behalf of itself and its Affiliates, not to, directly or indirectly, challenge the validity or enforceability of the '218 Patent or the '222 Patent (or assist any Third Party to do so) in any proceedings before the USPTO. Notwithstanding the foregoing, this Section 7 does not prevent the Sandoz Parties from commencing such proceedings before the USPTO in response to a claim by the Cadence Parties against the Sandoz Parties of infringement of the '218 Patent or the '222 Patent by any ANDA that is not the Sandoz ANDA or any product that is not the Sandoz Product.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

8. **Confidentiality.** The terms of the Settlement Documents and the negotiations of the Parties pertaining thereto shall be maintained in confidence by the Parties except as is: (i) required by statute, ordinance or regulation, including, without limitation, SEC reporting requirements, or by the rules or regulations of any stock exchange that a Party is subject to; (ii) required pursuant to compulsory legal process or by discovery obligations incident to litigation; (iii) necessary for the exercise of the rights granted to the Parties under the Settlement Documents, including that the Sandoz Parties may disclose such terms to the US FDA as may be reasonably necessary in obtaining and maintaining final approval of the Sandoz ANDA and launching the Sandoz Product that is the subject of the Sandoz ANDA, when and only when as provided by the Term Sheet; (iv) expressly provided in the Settlement Documents; or (v) expressly permitted under this Section 8, or as otherwise agreed to in writing by the Parties.

(a) If a Party is disclosing information relating to any of the Settlement Documents because it is required to do so to comply with statutory, regulatory, or legal process requirements (or necessary for the exercise of the rights granted under the Settlement Documents), including its reporting requirements under the SEC rules, or any national securities exchange on which it is listed, such Party intending to make such disclosure shall give the other Parties at least [***] prior notice in writing of the text of the intended disclosure, unless such statutory, regulatory, or legal process requirements would require earlier disclosure, in which event, such notice shall be provided as early as practicable.

(b) Such disclosing Party shall request confidential treatment with respect to the terms of the applicable Settlement Documents and to use Commercially Reasonable Efforts to have redacted such provisions of the applicable Settlement Documents as the Parties may agree from any copies filed pursuant to such statutory, regulatory, or legal process requirements. Without limiting the generality of the foregoing, if a Party determines that it will be required to file the Settlement Documents as provided above, promptly after the giving of notice by such Party as contemplated above, the Parties shall use Commercially Reasonable Efforts to agree on those provisions of the Settlement Documents that the Parties will seek to have redacted as provided above.

(c) Each Party may disclose the terms of the Settlement Documents to its respective Affiliates, insurers, lenders, attorneys, and accountants, subject to such Affiliates, insurers, lenders, attorneys, accountants, and potential investors, acquirors or merger partners, being bound by confidentiality obligations at least as stringent as those set forth in this Section 8.

9. **Public Documents.** The Parties recognize that, once it is filed with the District Court, the Stipulation and Order of Dismissal With Prejudice will be a matter of public record and therefore will not be subject to any confidentiality restrictions herein. The Parties also recognize that, upon the filing of the Stipulation and Order of Dismissal With Prejudice with the District Court, the fact that the Parties have settled the Pending Litigation will be a matter of public record and thus will not be subject to any confidentiality restrictions herein; provided, however, that, subject to the terms of the Term Sheet, the terms of such settlement shall be maintained in confidence as provided by Section 8 above.

10. **Press Release.** Except as permitted hereunder or under the Term Sheet, the terms of the Settlement Documents shall remain confidential.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

11. General Provisions.

- (a) The Settlement Documents contain the entire settlement terms pertaining to the subject matter hereof, and supersede any prior or contemporaneous negotiations, representations, settlement agreements, and understandings of the Parties with respect to such subject matter, whether written or oral. The Parties acknowledge that they have not relied on any promise, representation, or warranty, expressed or implied, not contained in the Settlement Documents.
- (b) This Settlement Agreement is the result of good faith negotiations and compromise. The Settlement Agreement and the releases contained in this Settlement Agreement affect the Pending Claims, and, except as expressly set forth in this Settlement Agreement, nothing set forth herein shall be construed as an admission by any Party hereto of any liability of any kind to the other, or to any other Person.
- (c) Each of the Parties covenants and agrees, severally and for itself and its Affiliates only, to take additional actions that may be reasonably necessary or appropriate to fully effectuate the terms, intent, and conditions of this Settlement Agreement.
- (d) This Settlement Agreement shall inure to the benefit of the Parties and, consistent with the assignment provisions set forth in the Term Sheet, shall be binding upon the Parties and their respective successors and permitted assigns.
- (e) Each Party acknowledges and agrees that money damages would not be a sufficient remedy for any breach of this Settlement Agreement or the Term Sheet by another Party, as the case may be, and that the non-breaching Party or Parties will be entitled to equitable relief, including a temporary restraint, a preliminary injunction, a permanent injunction, and specific performance for any such breach. Such remedies are not to be the exclusive remedies for a breach of this Settlement Agreement or the Term Sheet, but will be in addition to all other remedies available at law or equity.
- (f) This Settlement Agreement will be deemed to have been drafted jointly by the Parties and therefore no provision of this Settlement Agreement shall be construed against any Party on the theory that a particular Party drafted such provision.
- (g) This Settlement Agreement shall be governed by and construed in accordance with the laws of the State of California without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any jurisdiction other than the State of California. All actions and proceedings arising out of or relating to this Settlement Agreement or the Term Sheet shall be heard and determined exclusively in the District Court, and each Party irrevocably waives, and agrees not to assert by way of motion, defense, or otherwise, in any such action or proceeding, any claim that it is not subject personally to the jurisdiction of the District Court, that its property is exempt or immune from attachment or execution, that such action or proceeding is brought in an inconvenient forum, that the venue of such action or proceeding is improper, or that this Settlement Agreement or the Term Sheet or the transactions contemplated hereby or thereby may not be enforced in or by the District Court. In the event that the District Court lacks subject-matter jurisdiction, the provisions of this paragraph apply equally to the California state courts.
- (h) This Settlement Agreement may be executed simultaneously in any number of counterparts, and sent via facsimile or e-mail to the other Parties, each of which when so executed and delivered shall be taken to be an original, but such counterparts shall together constitute but

one and the same document. Telefacsimile or e-mail transmissions of any executed original counterpart signature page to this Settlement Agreement and/or retransmission of any such executed telefacsimile or e-mail transmission shall be deemed to be the same as the delivery of an executed original and the Parties may not claim any defect based upon another Party's inability to produce a "hard" signature copy. At the request of a Party, a Party shall confirm fax transmissions by executing duplicate original documents and delivering the same to the requesting Party.

(i) Headings in this Settlement Agreement are for convenience of reference only and shall not affect its interpretation or construction.

(j) Each Party shall bear its own costs, fees, and expenses in any way related to the negotiation, preparation, execution, and delivery of this Settlement Agreement and the obligations and releases contained herein.

(k) Assignment of this Settlement Agreement is subject to the same terms and conditions as the assignment of the Term Sheet, and this Settlement Agreement may be assigned only in connection with (and to the assignee of) an assignment of the Term Sheet. Notwithstanding anything in this Settlement Agreement to the contrary, assignment of this Settlement Agreement shall not release any claims against a Person that is not a Party or an Affiliate of a Party on the Execution Date.

(l) Subject to Section 2, if any provision of the Settlement Documents shall be held illegal or unenforceable, that provision shall be limited or eliminated to the minimum extent necessary so that the Settlement Documents shall otherwise remain in full force and effect and enforceable, provided that nothing contained in the Settlement Documents shall be deemed to require a Party to agree to any modification that materially affects the economic value of the transactions contemplated hereby.

(m) As used in this Settlement Agreement, neutral pronouns and any variations thereof shall be deemed to include the feminine and masculine and all terms used in the singular shall be deemed to include the plural, and vice versa, as the context may require. The words "herein," "hereof" and "hereunder" and other words of similar import refer to this Settlement Agreement as a whole, as the same may from time to time be amended or supplemented, and not to any particular subdivision contained in this Settlement Agreement. The word "including" when used herein is not intended to be exclusive, or to limit the generality of the preceding words, and means "including, without limitation". Where a Party's consent is required hereunder, except as otherwise specified herein, such Party's consent may be granted or withheld in such Party's sole discretion.

12. Notices. All notices pursuant to this Settlement Agreement shall be provided, by (a) fax or e-mail, followed by sending a copy by first class mail or express delivery service, or (b) first class mail or express delivery service, as follows and shall be deemed effective upon receipt of same:

If to the Cadence Parties:

Cadence Pharmaceuticals, Inc.
12481 High Bluff Drive, Suite 200
San Diego, California 92130

Attention: Hazel M. Aker, General Counsel
Phone: [***]
Fax: [***]
Email: [***]

and

Kenneth Schuler
Latham & Watkins
233 South Wacker Drive, Suite 5800
Chicago, IL 60606
Phone: [***]
Fax: [***]
Email: [***]

and

SCR Pharmatop
10, Square St. Florentin
78150 Le Chesnay, France
Attention: Managing Director
Phone: [***]
Fax: [***]
Email: [***]

and

Didier Ravaud
SCP Ayme Ravaud Leguen
10 rue Cimarosa 75116
Paris, France
Phone: [***]
Fax: [***]
Email: [***]

and

Charles Weiss
Holland & Knight LLP
31 West 52nd Street
New York NY 10019
Phone: [***]
Fax: [***]
Email: [***]

and

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

John S. Moot
Schwartz Semerdjian Ballard & Cauley LLP
101 West Broadway, Suite 810
San Diego, CA 92101
Phone: [***]
Fax: [***]
Email: [***]

If to Sandoz:

Sandoz Inc.
506 Carnegie Center, Suite 400
Princeton, New Jersey 08540
Attention: General Counsel
Fax: [***]

with copy to:

Sandoz Inc.
506 Carnegie Center, Suite 400
Princeton, New Jersey 08540
Attention: Vice President, Intellectual Property
Fax: [***]

If to Neogen:

Legal Department
Neogen International N.V.
Square Marie Curie 50, building 5, 4th floor
1070 Anderlecht
Belgium
Phone: [***]
Fax: [***]

If to APC:

APC Pharmaceuticals, LLC
Managing Director
40 Oriole Drive
Medfield, MA 02052
Phone: [***]
Fax: [***]

[Signature Page Follows]

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the Parties hereto have each caused this Settlement Agreement to be executed by their authorized representatives as of the Execution Date.

Cadence Pharmaceuticals, Inc.

By /s/ William R. LaRue
Name: William R. LaRue
Title: Sr. Vice President and CFO

SCR Pharmatop

By /s/ Dietlin
Name: Dietlin
Title: General Manager

Sandoz Inc.

By /s/ Pearl Siew
Name: Pearl Siew
Title: VP & Head, IP US

Sandoz AG

By /s/ Georg Rieder
Name: Georg Rieder
Title: Chief Financial Officer, Sandoz AG

Neogen International N.V.

By /s/ Eric DuBois
Name: Eric DuBois
Title: Managing Director

APC Pharmaceuticals, LLC

By /s/ John F. Kiley
Name: John F. Kiley
Title: Managing Director

By /s/ Andreas Eggmann
Name: Andreas Eggmann
Title: Head Sandoz AG

EXHIBIT A

Stipulation and Order of Dismissal With Prejudice

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

_____))
CADENCE PHARMACEUTICALS, INC. AND)
SCR PHARMATOP,)
)
Plaintiffs,)
) CASE NO. 13 CV-00278 DMS
v.)
) (MDD)
SANDOZ INC., SANDOZ AG, NEOGEN)
INTERNATIONAL N.V. AND APC)
PHARMACEUTICALS LLC)
)
Defendants.)
_____))

STIPULATION TO ORDER OF DISMISSAL
PURSUANT TO FED. R. CIV. P. 41(a)(2)

Pursuant to Rule 41(a)(2) of the Federal Rules of Civil Procedure, the Plaintiffs, Cadence Pharmaceuticals, Inc. and SCR Pharmatop, and Defendants Sandoz Inc., Sandoz AG, Neogen International N.V. and APC Pharmaceuticals LLC (collectively "the Parties") hereby stipulate to the entry of the attached proposed Order of Dismissal, dismissing with prejudice all claims, counterclaims, and defenses in the above-styled action as between the Parties, with the Parties bearing their own fees and costs.

LATHAM & WATKINS LLP

Stephen P. Swinton
Darryl H. Steensma
12636 High Bluff Drive, Suite 400
San Diego, CA 92130
Phone: [***]
Fax: [***]
Email: [***]
Email: [***]

Attorneys for Plaintiffs
Cadence Pharmaceuticals, Inc.
and SCR Pharmatop

OF COUNSEL:

LATHAM & WATKINS LLP

Kenneth G. Schuler, Esq.
233 S. Wacker, Suite 5800
Chicago, Illinois 60606
Telephone No.: [***]

Attorneys for Plaintiff
Cadence Pharmaceuticals, Inc.

HOLLAND & KNIGHT LLP

Charles A. Weiss, Esq.
31 West 52nd Street
New York, NY 10019
Telephone No.: [***]

Attorneys for Plaintiff
SCR Pharmatop

MORRIS POLICH & PURDY LLP

Donald L. Ridge
Megan S. Wynne
Noushan Nouredini
Morris Polich & Purdy LLP
1055 West Seventh Street, Suite 2400
Los Angeles, California 90017
Phone: [***]
Fax: [***]
Email: [***]
[***]
[***]

Attorneys for Defendants
Sandoz Inc., Sandoz AG, Neogen International N.V. and
APC Pharmaceuticals LLC

OF COUNSEL:

RAKOCZY MOLINO MAZZOCHI SIWIK LLC

William A. Rakoczy
Paul J. Molino
Deanne M. Mazzochi
Rachel P. Waldron
Rakoczy Molino Mazzochi Siwik LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60654
Phone: [***]
Fax: [***]
Email: [***]
[***]
[***]
[***]

Attorneys for Defendants
Sandoz Inc. and Sandoz AG

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

MILORD & ASSOCIATES, PC

Milord A. Keshishian
Milord & Associates, PC
2049 Century Park East, Suite 3850
Los Angeles, CA 90067
Ph: [***]
Fax: [***]
www.milordlaw.com

Attorneys for Defendant
APC Pharmaceuticals LLC

MERCHANT & GOULD P.C.

Jeffrey D. Blake
Merchant & Gould P.C.
191 Peachtree Street, N.E., Suite 4300
Atlanta, Georgia 30303-1740
Phone: [***]
Fax: [***]
Email: [***]

Attorneys for Defendant
Neogen International N.V.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

CADENCE PHARMACEUTICALS, INC. AND)	
SCR PHARMATOP,)	
)	
Plaintiffs,)	
)	CASE NO. 13 CV-00278 DMS
v.)	
)	(MDD)
SANDOZ INC., SANDOZ AG, NEOGEN)	
INTERNATIONAL N.V. AND APC)	
PHARMACEUTICALS LLC)	
)	
Defendants.)	
)	
)	

[Proposed] ORDER OF DISMISSAL

Pursuant to Rule 41(a)(2) of the FEDERAL RULES OF CIVIL PROCEDURE, and pursuant to and based on the stipulation of Plaintiffs, Cadence Pharmaceuticals, Inc. and SCR Pharmatop, and Defendants Sandoz Inc., Sandoz AG, Neogen International NV and APC Pharmaceuticals LLC (collectively “the Parties”), it is hereby ORDERED that all claims, counterclaims and defenses in the above-styled action as between the Parties, are dismissed with prejudice. The Parties shall bear their own fees and costs.

SO ORDERED:

This __ day of _____, 2014

Honorable Dana M. Sabraw
United States District Court Judge

EXHIBIT B

Term Sheet

[ATTACHED]

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CADENCE/SCR PHARMATOP-SANDOZ TERM SHEET

Cadence Pharmaceuticals, Inc. ("Cadence") and SCR Pharmatop ("Pharmatop" and, together with Cadence, the "Cadence Parties"), on the one hand, and Sandoz Inc. ("Sandoz Inc."), Sandoz AG ("AG" and, together with Sandoz Inc., "Sandoz"), Neogen International N.V. ("Neogen") and APC Pharmaceuticals, LLC ("APC" and, together with Sandoz and Neogen, the "Sandoz Parties"), on the other hand, have had discussions to resolve the Pending Litigation (as defined below), including the negotiation of rights and obligations in connection therewith and certain commercial terms, and each Party has determined that it is in its best interests to execute and be bound by this term sheet in connection therewith (this "Term Sheet"). Each of the Cadence Parties and the Sandoz Parties is referred to as a "Party" and, collectively, as the "Parties". This Term Sheet shall be considered to be confidential information of the Parties.

Accordingly, in addition to that certain Settlement Agreement entered into by the Cadence Parties and the Sandoz Parties, the Parties are executing this Term Sheet as of the date set forth on the signature page hereto (the "Execution Date") intending to be legally bound by the terms set forth herein and to create legally enforceable obligations and rights as set forth herein. Immediately following the execution of this Term Sheet, the Parties shall negotiate in good faith the terms of a definitive agreement regarding the transaction described in, and incorporating the terms set forth in, this Term Sheet (the "Definitive Agreement") and containing such other provisions that are usual and customary in a pharmaceutical industry license agreement, which Definitive Agreement, when executed by the Parties shall supersede and replace in its entirety this Term Sheet; provided, however, that if, despite such good faith efforts, the Parties are unable to negotiate the Definitive Agreement within [***] following the Execution Date, then all provisions in this Term Sheet shall continue to be binding on the Parties, provided that the Settlement Agreement has not been terminated in accordance with the terms hereof.

Overview

To resolve the Pending Litigation and any other disputes involving the Sandoz ANDA (as defined below) and the Sandoz Product (as defined below), the Parties are entering into this Term Sheet and shall negotiate in good faith the Definitive Agreement, which shall contain all of the terms and conditions set forth hereafter, and such other terms and conditions of the type normally included in such agreements that are consistent with this Term Sheet.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

Definitions

“222 Patent” means U.S. Patent No. 6,028,222, including all extensions, continuations, continuations-in-part, divisionals, reissues, reexaminations, inter partes reviews, and post-grant reviews thereof, and any foreign counterparts or equivalents thereof (regardless of whether any claim of priority is asserted or otherwise exists), in each case whether granted or allowed before, on, or after the Execution Date.

“218 Patent” means U.S. Patent No. 6,992,218, including all extensions, continuations, continuations-in-part, divisionals, reissues, reexaminations, inter partes reviews, and post-grant reviews thereof, and any foreign counterparts or equivalents thereof (regardless of whether any claim of priority is asserted or otherwise exists), in each case whether granted or allowed before, on, or after the Execution Date.

“Affiliate” means

- (a) A Person, which directly or indirectly controls a Party;
- (b) A Person, which is directly or indirectly controlled by a Party; or
- (c) A Person, which is controlled, directly or indirectly, by the ultimate parent company of a Party.

[***]

Control, as used in clause (a), (b), or (c), is defined as owning greater than fifty percent (>50%) of the voting stock of a company or having otherwise the power to govern the financial and the operating policies or to appoint the management of an organization.

“ANDA” means an abbreviated new drug application (or equivalent US regulatory mechanism).

“Authorized Generic” means a generic version of the Cadence Product (as defined below) that is marketed or intended for marketing in the Territory (as defined below) under the Cadence NDA (as defined below) without the OFIRMEV® trademark (or any replacement trademark).

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

“Cadence NDA” means NDA No. 022450, including any replacement, amendment, or supplement thereto.

“Cadence Product” means Cadence’s injectable acetaminophen product having a dosage amount of 1000 mg/100 ml (10 mg/ml) in finished dosage form that is the subject of the Cadence NDA.

“Commercially Reasonable Efforts” means the reasonable, diligent, and good-faith efforts as a pharmaceutical company of similar size to the corresponding Party would normally use to accomplish a similar objective under similar circumstances.

“District Court” means the United States District Court for the Southern District of California.

“Execution Date” means the date on which all the Parties have executed this Term Sheet and the Settlement Agreement.

“FDA” means the U.S. Food and Drug Administration (and any successor agency thereto).

“Final Court Decision” means a decision by a court that is no longer subject to a right of appeal (other than by a petition to the United States Supreme Court for writ of certiorari).

“First Filer” shall mean a first applicant, as defined under 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (as amended or replaced), and wherein such first applicant has not forfeited, waived or otherwise relinquished its generic exclusivity period.

“Generic Product” means an injectable acetaminophen drug formulation that is approved under the Federal Food, Drug, and Cosmetic Act under section 505(b)(2) or 505(j) of the Act, that relied in whole or in part on data developed for, or the approval of, the Cadence Product.

“Launch at Risk” means commercial Marketing of a Generic Product by a Third Party that is (i) prior to the earlier of (a) the Entry Date (as defined below) or (b) a Final Court Decision that such Third Party’s Generic Product does not infringe any valid unexpired claim of the ’218 Patent and the ’222 Patent; and (ii) not licensed or otherwise authorized by the Cadence Parties prior to the date of such Marketing commencement.

“Licensed Patents” means, collectively, the '218 Patent, and any other United States patents owned, licensed by, or otherwise controlled by the Cadence Parties that would, in the absence of a license, be infringed by the Manufacture, importation and/or Marketing by any of the Sandoz Parties of the Sandoz Product in the Territory as of the Entry Date, including any extensions, Pediatric Exclusivities, continuations, continuations-in-part, divisionals, reissues, reexaminations, inter partes reviews, and post-grant reviews thereof, and any foreign counterparts or equivalents thereof (regardless of whether any claim of priority is asserted or otherwise exists).

“Manufacture” means to use, make, or have made a product.

“Market” and “Marketing” means to offer for sale, sell, or distribute a product.

[***]

“NDA” means a new drug application (or equivalent US regulatory mechanism).

“Officially Discontinue” means any of: (a) delisting the Cadence Product with the FDA; (b) seeking or otherwise undertaking any action with the FDA to withdraw the Cadence Product from the market; and/or (c) deleting, removing, designating as “obsolete” or canceling any National Drug Code(s) or any other relevant code(s) for the Cadence Product from the applicable National Drug Data File maintained by First Databank (or any successor or equivalent organization), or from any other pricing database.

“Orange Book” means the FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (or any successor publication thereto).

“Pediatric Exclusivity” means the period of exclusivity provided by 21 U.S.C. § 355a(b)(1)(B) (as amended or replaced) and/or 21 U.S.C. § 355a(c)(1)(B) (as amended or replaced).

“Pending Litigation” means *Cadence Pharmaceuticals, Inc. and*

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“Person” means an individual, partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, governmental authority, or other entity of whatever nature.

“Sandoz ANDA” means ANDA No. 204052 filed by Sandoz Inc. with the FDA seeking the FDA’s approval to sell generic injectable acetaminophen in the United States, including any amendments, supplements or replacements thereto, and that references the Cadence Product.

“Sandoz ANDA Holder” means the registered holder of the Sandoz ANDA.

“Sandoz Product” means an injectable acetaminophen product having a dosage amount of 1000 mg/100 ml (10 mg/ml) in finished dosage form that is the subject of the Sandoz ANDA.

“Territory” means the United States of America, including its territories, possessions, and commonwealths.

“Third Party” means any Person other than a Party or its Affiliates.

License

Subject to the terms and conditions of this Term Sheet and the Settlement Agreement, Cadence hereby grants to Sandoz ANDA Holder (and to the extent necessary, their Affiliates, suppliers, distributors, manufacturers, customers and assignees, as the case may be) a non-exclusive, fully paid, non-transferable sublicense under the Licensed Patents, with no right to sublicense (the “License”), to:

- (a) Manufacture the Sandoz Product inside or outside the Territory not earlier than [***] and solely for Marketing the Sandoz Product in the Territory [***];
- (b) Import the Sandoz Product into the Territory not earlier than [***] and solely for Marketing the Sandoz Product in the Territory [***]; and
- (c) Market the Sandoz Product in the Territory [***].

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- (a) Not earlier than [***], the Sandoz Parties may engage in [***]; and
- (b) Not earlier than [***], the Sandoz Parties may offer the Sandoz Product for sale to occur on or after the Entry Date in the Territory (provided, however, that none of the Sandoz Parties, nor any of their respective Affiliates, will enter into any binding contract for, accept orders for or deliver to any Third Party, any Sandoz Product prior to the Entry Date).

Entry Date

The "Entry Date" shall be December 6, 2020, subject to any of the accelerations described below.

Acceleration of Entry Date

The Entry Date shall be accelerated only under the circumstances specified below to the earliest of:

- (a) Final Court Decision/Expiration of Patents. In the event of a Final Court Decision in a patent case other than an appeal from the USPTO in a reexamination, which is provided for below, holding all unexpired, then asserted and adjudicated claims of the '218 Patent and the '222 Patent to be (i) invalid or unenforceable and/or (ii) not infringed by a Generic Product prior to the Entry Date, then the Entry Date shall automatically be accelerated and amended to the date that is the earlier of:
 - (w) [***] after the date on which a Third Party commences Marketing a Generic Product after the date of entry of a Final Court Decision under subpart (a)(i) or (a)(ii), if such Third Party is a First Filer;
 - (x) the date of entry of a Final Court Decision under subpart (a)(i) above, if, as of such date, there is no First Filer (including as a result of forfeiture, waiver or other relinquishment of generic marketing exclusivity);
 - (y) the date on which a Third Party commences Marketing a Generic Product, consistent in size and scope of a commercial launch thereof, after the date of entry of a Final Court Decision under subpart (a)(ii) above, if, as of such date, there is no First Filer (including as a result of forfeiture, waiver or other relinquishment of generic marketing exclusivity); or

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- (z) the date on which the '222 Patent expires in the event that only the '218 Patent has been the subject of a Final Court Decision under either subpart (a)(i) or (a)(ii), above.

In addition, if the Cadence Parties fail to maintain the Licensed Patents, the Entry Date may be accelerated to the last to expire of the Licensed Patents.

For the sake of clarity, in the event of a final decision of the USPTO in a re-examination from which no appeal can be or has been taken that results in the issuance of a Reexamination Certificate cancelling all relevant claims such that a Third Party may commence Marketing a Generic Product, the Entry Date shall automatically be accelerated and amended to the date on which a Third Party commences Marketing a Generic Product; *provided, however*, that no such acceleration and amendment shall occur if such Reexamination Certificate contains one or more claims that:

- (i) are not materially different from dependent claims asserted against the Sandoz Parties in the Pending Litigation but were rewritten in independent form (or with different dependent form) because the claim(s) from which they depended were cancelled in the Reexamination Certificate;
 - (ii) would necessarily be infringed by the Sandoz Product if the Sandoz Product were assumed to infringe the claims asserted against Sandoz in the Pending Litigation; or
 - (iii) are “substantially identical” (as that term is used in 35 U.S.C. § 252) to a claim asserted against the Sandoz Parties in the Pending Litigation.
- (b) Previously Licensed Generic Product. In the event that Cadence has licensed or otherwise authorized any Third Party to Market a Generic Product before December 6, 2020, then the Entry Date shall automatically be accelerated and amended to the date that is: (i) [***] after the date on which any Third Party commences Marketing a Generic Product in the Territory in the event that such Third Party is a First Filer; or (ii) the date on which any Third Party that is licensed or otherwise authorized to commence Marketing a Generic

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Product commences Marketing a Generic Product in the Territory if such Third Party is not a First Filer. Cadence shall provide Sandoz with notice of any anticipated Third Party Marketing of a Generic Product, under either subpart (b)(i) or (b)(ii) herein, within [***] of execution of such Third Party's license or authorization.

- (c) Authorized Generic. In the event that Cadence Markets (either itself or through an Affiliate) or licenses a Third Party to Market an Authorized Generic before December 6, 2020, then Sandoz's Entry Date shall automatically be accelerated and amended to be the date on which such Authorized Generic is first Marketed in the Territory. Cadence shall provide Sandoz with notice of any anticipated Marketing of an Authorized Generic within [***] of execution of any agreement that permits the Marketing of an Authorized Generic.
- (d) Market Decline. In the event that (i) any of the Sandoz Parties, after [***], sends Cadence a report from [***], or other mutually acceptable sales report, demonstrating that unit sales of the Cadence Product for have declined to less than [***] and (ii) such report is substantiated by Cadence by reference to a similar report for the same period from [***] (a "Market Decline"), it being acknowledged and agreed that Cadence shall have provided a copy of its report to Sandoz within [***] after Cadence's receipt of the [***], then, the Entry Date shall be the [***] following Cadence's receipt of the report from the Sandoz Parties; provided, however, that in the event such decline is (x) the result of or attributable to (1) [***], or (2) [***], and/or (y) not substantiated by Cadence's report provided in accordance with clause (ii) above, then a Market Decline shall not be deemed to have occurred.
- (e) Launch at Risk. In the event of a Launch At Risk, the Entry Date shall be the date of such Launch At Risk, provided that (i) the Sandoz ANDA Holder has secured final approval of the Sandoz ANDA from the FDA; and (ii) the Sandoz ANDA Holder is not enjoined from entering the market; and provided further that if Cadence seeks, within [***] of the date that the Sandoz ANDA Holder provides written notice to Cadence of such Launch At Risk, a temporary restraining order or injunction prohibiting further sale of such Generic Product, or Cadence otherwise enters into an agreement with

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such Third Party to prohibit further sale of such Generic Product, the Entry Date shall not be deemed to have been accelerated or amended prior to a court decision on Cadence's application for a temporary restraining order or, if pending, its application for an injunction. Entry of a court order denying Cadence's application for a temporary restraining order and injunction shall be deemed to constitute an "Entry Date"; but if a temporary restraining order or an injunction is issued against such Third Party, then no accelerated "Entry Date" shall be deemed to have occurred, provided that no Generic Product is being Marketed in the Territory, unless the Entry Date has otherwise occurred as provided under this Term Sheet. If the application for an injunction is initially denied but the Third Party is subsequently enjoined from continued Marketing of its Generic Product by grant of an injunction, then the Sandoz ANDA Holder shall not commence Marketing the Sandoz Product, or if the Sandoz ANDA Holder has already commenced Marketing the Sandoz Product it shall immediately exit the market with the Sandoz Product (provided that no Generic Product is being Marketed in the Territory), unless the Entry Date has otherwise occurred as provided under this Term Sheet. In the event the Sandoz ANDA Holder has exited the market based upon the previous two sentences, the Sandoz ANDA Holder shall retain its rights to Market an Authorized Generic product, subject to the terms of this Term Sheet.

- (f) Subsequent License. In the event that, after the Execution Date, the Cadence Parties license or otherwise authorize a Third Party to Market a Generic Product prior to the Entry Date set forth in this Term Sheet, then the Entry Date shall be automatically accelerated to the date that is (i) [***] after the date on which such Third Party commences Marketing a Generic Product in the Territory in the event that such Third Party is a First Filer; or (ii) the date on which such Third Party is permitted to launch a Generic Product if such Third Party is not a First Filer, provided that the Sandoz ANDA Holder has obtained final approval from the FDA for the Sandoz Product by such prior Entry Date. The Cadence Parties shall provide the Sandoz ANDA Holder with notice of any such earlier Entry Date within [***] of entering into such Third Party agreement.

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Authorized Generic Rights/Option

In the event that Perrigo or Paddock or any of their Affiliates elects in writing not to exercise its rights to Market an Authorized Generic, then Cadence shall promptly provide written notice of such election to the Sandoz ANDA Holder and Cadence shall thereafter grant a similar right of first refusal for the Sandoz ANDA Holder to be the sole and exclusive distributor of an Authorized Generic (a "Cadence Authorized Generic Product") in the Territory, subject to the Parties' negotiation in good faith of a written agreement on substantially the same commercial terms as those set forth in any agreement between Cadence and Paddock in connection therewith.

Covenant-Not-To-Sue

Subject to each of the Sandoz Parties' compliance with the terms of this Term Sheet, the Cadence Parties covenant not to assert (i) the Licensed Patents or any other United States or foreign patent rights owned, licensed or otherwise controlled by the Cadence Parties or their Affiliates against the Manufacture or Marketing of the Sandoz Product in or for the Territory or the importation of the Sandoz Product or active pharmaceutical ingredient ("API") into the Territory by any of the Sandoz Parties; or (ii) any foreign patent rights owned, licensed or otherwise controlled by the Cadence Parties or their Affiliates against the Manufacture of the Sandoz Product or API outside of the Territory solely for the Marketing of the Sandoz Product in the Territory or the importation of the Sandoz Product into the Territory by any of the Sandoz Parties (the "Covenant"). For the avoidance of doubt, no right, license, or covenant is granted as to Marketing of Sandoz Product or API outside the Territory. Each of the Parties hereby acknowledges and agrees that, pursuant to that certain letter dated January 30, 2014 from Bristol-Myers Squibb Company ("BMS") to counsel for each of the Parties, BMS has waived any right to consent to settlement of the Pending Litigation and, accordingly, no obligation under this License Agreement, including the Covenant, or the Settlement Agreement shall be imposed upon BMS.

For all patents listed in the Orange Book for the Cadence Product, the foregoing Covenant shall hereby be treated as a non-exclusive license to such patents for the Sandoz Product solely for the purpose of allowing the Sandoz ANDA Holder to file and maintain with the FDA a "Paragraph IV Certification" for the Sandoz ANDA under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (as amended or replaced) with respect thereto. The Sandoz ANDA Holder shall have the right to maintain its existing "Paragraph IV Certification" under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (as amended or replaced) against the '218 Patent, and as to any other patent listed in the FDA's Orange Book

now or in the future in connection with the Cadence Product.

Subject to each of the Cadence Parties' compliance with the terms of this Term Sheet, the Sandoz Parties covenant not to assert (i) the [***] or any other United States or foreign patent rights owned, licensed or otherwise controlled by the Sandoz Parties or their Affiliates against the Manufacture or Marketing of the Cadence Product in or for the Territory or the importation of the Cadence Product or API into the Territory by any of the Cadence Parties; or (ii) any foreign patent rights owned, licensed or otherwise controlled by Neogen or its Affiliates against the Manufacture of the Cadence Product or API outside of the Territory solely for the Marketing of the Cadence Product in the Territory or the importation of the Cadence Product into the Territory by any of the Cadence Parties.

No Challenge to Licensed Patents

From and after the Execution Date, each of the Sandoz Parties agrees, on behalf of itself and its Affiliates, not to, directly or indirectly, challenge the validity or enforceability of the Licensed Patents (or assist any Third Party to do so) in any court or forum, including by suing, directly or indirectly, the Cadence Parties or any of their respective Affiliates in any action in any forum seeking an order or decision that (i) any of the Licensed Patents is invalid or unenforceable or (ii) the manufacture, use or sale of any product that is the subject of the Sandoz ANDA does not infringe the Licensed Patents.

Notwithstanding the foregoing or anything else in the Term Sheet, the Definitive Agreement or the Settlement Agreement, the previous paragraph does not prevent any of the Sandoz Parties from challenging the validity, enforceability or non-infringement of a Licensed Patent in judicial proceedings in connection with any product other than the Sandoz Product or any ANDA other than the Sandoz ANDA, including but not limited to the filing of any "Paragraph IV Certification" under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (as amended or replaced) to any Licensed Patent as part of any ANDA that is not the Sandoz ANDA, the filing of any declaratory judgment action against any Licensed Patent, and engaging in the defense of, or in response to, a patent infringement lawsuit or proceeding asserting any Licensed Patent, in each case in connection with (i) any ANDA that is not the Sandoz ANDA or (ii) any product that is not the Sandoz Product.

From and after the Execution Date, each of the Sandoz Parties agrees, on behalf of itself and its Affiliates, not to, directly or indirectly, challenge the validity or enforceability of the Licensed

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Patents (or assist any Third Party to do so) in any proceedings before the USPTO. Notwithstanding the foregoing or anything else in the Term Sheet, the Definitive Agreement or the Settlement Agreement, this paragraph does not prevent the Sandoz Parties from commencing such USPTO proceedings in response to a claim by the Cadence Parties against the Sandoz Parties of infringement of any Licensed Patent by any ANDA that is not the Sandoz ANDA or any product that is not the Sandoz Product.

Representations and Warranties

(a) Each Party represents and warrants to the other Parties that:

- (i) It has the corporate, partnership or limited liability company power and authority to enter into this Term Sheet and to perform its obligations hereunder;
- (ii) The execution, delivery and performance of this Term Sheet have been duly authorized by all necessary corporate or other organizational actions of the Party and its Affiliates; and
- (iii) The execution and delivery of this Term Sheet and the performance by the Party of any of its obligations hereunder do not and will not conflict with or result in a breach of any other agreement to which it or any of its Affiliates is a party, any judgment of any court or governmental body applicable to the Party or its properties, or, to the Party's knowledge, any statute, decree, order, rule or regulation of any court or governmental authority applicable to the Party or its properties; and
- (iv) Upon execution and delivery of this Term Sheet by all Parties, this Term Sheet is a valid obligation binding upon such Party and enforceable in accordance with its terms except as enforceability may be limited in future bankruptcy or insolvency.

(b) Each of the Sandoz Parties represents and warrants to the Cadence Parties that, as of the Execution Date, Sandoz and Neogen own all right, title and interest in and to the Sandoz ANDA, no other Person has any rights under the Sandoz ANDA, and neither Sandoz nor Neogen has transferred or assigned any of their rights under the Sandoz ANDA to any Person.

(c) Each of the Cadence Parties represents and warrants to the

Sandoz Parties that with the rights granted to the Sandoz Parties in this Term Sheet, BMS does not have the right to assert the Licensed Patents, the '222 Patent, or any other United States or foreign patent rights exclusively licensed by BMS or its Affiliates to any of the Cadence Parties, against the Manufacture or Marketing of the Sandoz Product in or for the Territory, or the importation of the Sandoz Product or its active pharmaceutical ingredient into the Territory, by any of the Sandoz Parties, at any time as of or after the Execution Date.

(d) With the exception of the Cadence Parties' representation and warranty set forth above in subpart (c), no Party makes any express or implied warranties that any product or process can be made, used, sold, offered for sale, imported or distributed without infringing intellectual property rights owned or controlled by Third Parties.

Waiver of Regulatory or Statutory Exclusivities

Subject to the terms and conditions of this Term Sheet, Cadence grants a waiver of any regulatory or statutory exclusivities to the extent necessary to effectuate the License and the Covenant, and solely for Marketing the Sandoz Product in the Territory not earlier than the Entry Date ("Exclusivity Waiver"). Cadence agrees to cooperate reasonably with the Sandoz ANDA Holder to effectuate the selective waiver of regulatory exclusivity detailed herein, including providing notices to the FDA in substantially the form attached hereto as Exhibit A, verifying the existence of such selective waiver and not opposing the FDA's final approval of the Sandoz ANDA for sale of the Sandoz Product in the Territory as of the Entry Date. Cadence agrees to notify the Sandoz ANDA Holder within [***] of its receipt of notice regarding the grant or denial of Pediatric Exclusivity with respect to the Cadence Product. Cadence also agrees to deliver an executed version of Exhibit A (or such other form as FDA may require) to the FDA and the Sandoz ANDA Holder within [***] following the Sandoz ANDA Holder's request.

Most Favored Nation

As of and after the Execution Date, the Cadence Parties agree that if the Cadence Parties enter into any agreement, license, sublicense, settlement, covenant, waiver or other authorization of any kind with any Third Party (that is not a First Filer) or Affiliate involving a Generic Product or Authorized Generic ("Subsequent Third Party Agreement"), and any terms involving entry dates, accelerations, manufacturing and import rights, pre-marketing terms, covenants, or financial terms in such Subsequent Third Party Agreement are more favorable than those terms specifically set forth in this Term Sheet or the Definitive Agreement, then Cadence shall, as soon as reasonably practicable (and in no event less than [***]), amend the terms of this Term Sheet or the Definitive Agreement to extend such more favorable terms to Sandoz and provide notice of such amendment to Sandoz. The Cadence Parties further represent and warrant that, as of the Execution Date, they have not entered into any agreement, license, sublicense, settlement, covenant, waiver or other authorization of any kind with any Third Party (that is not a First Filer) in respect of a Generic Product that provides for more favorable terms relating to entry dates, accelerations, pre-marketing terms, covenants, or financial terms (with the explicit exception of any terms relating to an Authorized Generic).

Costs And Expenses

Each Party shall bear its own fees and costs, including attorney fees, in the Pending Litigation and in connection with the preparation and execution of this Term Sheet, the Settlement Agreement and the

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Confidentiality

The terms of this Term Sheet and the negotiations of the Parties pertaining thereto shall be maintained in confidence by the Parties except:

- (a) as may be disclosed to auditors and accountants or other consultants associated with tax reporting issues;
- (b) as is required by statute, ordinance or regulation (including pursuant to Title XI of the Medicare Prescription Drug Improvement and Modernization Act (Subtitle B – Federal Trade Commission Review)), including, without limitation, SEC reporting requirements, or by the rules or regulations of any stock exchange that the Parties are subject to;
- (c) as is required pursuant to compulsory legal process or by discovery obligations incident to litigation;
- (d) as is necessary for the exercise of the rights granted to the Parties under this Term Sheet, including that the Sandoz Parties may disclose such terms to (i) suppliers of products associated with the Sandoz Product as may be reasonably necessary for the Sandoz Parties to conduct business with such suppliers, provided that each of such suppliers agrees to be bound in writing to keep such disclosed terms in confidence and not to use any part of such disclosure for any other purpose, and (ii) the FDA as may be reasonably necessary in obtaining and maintaining final approval of the Sandoz ANDA and launching its Generic Product that is the subject of the Sandoz ANDA, when and only when as provided by this Term Sheet;
- (e) as expressly provided in this Term Sheet; or
- (f) as expressly permitted hereunder, or as otherwise agreed to in writing by the Parties.

If a Party is disclosing information relating to this Term Sheet because it is required to do so to comply with statutory, regulatory or legal process requirements, including its reporting requirements under the SEC rules, or any national securities exchange on which it is listed, such Party intending to make such disclosure shall give the other Party at least [***] prior notice in writing of the text of the intended disclosure, unless such statutory, regulatory or legal process

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requirements would require earlier disclosure, in which event, the notice shall be provided as early as practicable. A disclosing Party agrees to request confidential treatment with respect to the terms of this Term Sheet and to use Commercially Reasonable Efforts to have redacted such provisions of this Term Sheet as the Parties may agree from any copies filed pursuant to such statutory, regulatory or legal process requirements. If either Party determines that it will be required to file this Term Sheet as provided above, promptly after the giving of notice by such Party as contemplated above, the Parties will use commercially reasonable efforts to agree on those provisions of this Term Sheet that the Parties will seek to have redacted as provided above. Each Party may disclose the terms of this Term Sheet to their respective Affiliates, insurers, lenders, attorneys, and accountants, as well as to their respective potential investors, acquirors or merger partners, subject in each case to such Affiliates, insurers, lenders, attorneys and accountants, and potential investors, acquirors or merger partners, being bound by confidentiality obligations at least as stringent as those contained herein.

Non-Interference

Subject to each of the Sandoz Parties' compliance with the terms of this Term Sheet, the Cadence Parties shall not, and shall not cause, authorize or encourage any Third Party to, initiate or otherwise undertake any activity, directly or indirectly, against the Sandoz ANDA or the Sandoz Product to: (i) interfere with the Sandoz ANDA Holder's efforts to obtain FDA approval of the Sandoz Product and the Sandoz ANDA or (ii) interfere with a Sandoz Party's efforts to Manufacture and Market the Sandoz Product in accordance with the terms and provisions of this Term Sheet. Neither this Term Sheet nor this provision shall be interpreted as (x) the Cadence Parties consenting to approval from the FDA or any other applicable regulatory authority for any of the Sandoz Parties to market a product incorporating acetaminophen in the Territory or (y) preventing or prohibiting any of the Cadence Parties from filing or submitting any Citizen Petition in accordance with 21 C.F.R. § 314.127 (including the Citizen Petition filed by Cadence dated November 4, 2013) that are, or may be, filed solely for reasons of public safety or efficacy.

The Cadence Parties shall not, and shall not cause, authorize or encourage any Third Party to, Officially Discontinue the Cadence Product prior to expiration of the Licensed Patents.

No Admission

Nothing in the Agreement shall be construed as or deemed to be an admission by the Parties hereto, or any one of them, of any unlawful,

improper, or actionable conduct or omission by any of them, and each Party hereto expressly denies liability of any kind whatsoever.

Regulatory Delay

No provision of this Term Sheet shall be affected by any delay in the approval of the Sandoz ANDA by the FDA, or the failure of the Sandoz ANDA Holder to obtain FDA approval of the Sandoz ANDA.

Assignment

This Term Sheet shall not be assignable in whole or in part by any of the Parties without the prior written consent of all the other Parties. Notwithstanding the foregoing, Cadence may assign this Term Sheet to any of its Affiliates or to any successor or assign of the '222 Patent, the '218 Patent, or the OFIRMEV® business generally, and Sandoz, Neogen and APC may assign this Term Sheet to any of their respective Affiliates or Third Party who acquires all or substantially all of the business to which this Term Sheet relates, provided that in either case such Affiliate, successor, assign or Third Party, as the case may be, agrees in writing for the benefit of the non-assigning Party to assume all of the obligations of the assigning Party hereunder. In addition, Pharmatop may assign this Term Sheet to an assignee of the '218 Patent and '222 Patent, provided that any such assignee agrees in writing for the benefit of the Sandoz Parties to assume all of the obligations hereunder. The Agreement shall be binding upon, and inure to the benefit of, the successors and assigns of the Parties.

Governing Law

The Agreement shall be governed by and construed in accordance with the laws of the State of California without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any jurisdiction other than the State of California. All actions and proceedings arising out of or relating to this Term Sheet shall be heard and determined exclusively in the District Court, and each Party irrevocably waives, and agrees not to assert by way of motion, defense, or otherwise, in any such action or proceeding, any claim that it is not subject personally to the jurisdiction of the District Court, that its property is exempt or immune from attachment or execution, that such action or proceeding is brought in an inconvenient forum, that the venue of such action or proceeding is improper, or that this Term Sheet or the transactions contemplated hereby or thereby may not be enforced in or by the District Court. In the event that the District Court lacks subject-matter jurisdiction, the provisions of this paragraph apply equally to the California state courts.

**Construction/
Interpretation**

The headings and captions used in this Term Sheet are solely for the convenience of reference and shall not affect its interpretation. The term “including” means “including, without limitation,” and “herein,” “hereof,” and “hereunder” refer to this Term Sheet and this Term Sheet as a whole. The word “will” shall be construed to have the same meaning and effect as the word “shall.” The Parties agree and acknowledge that this Term Sheet and this Term Sheet is the product of both Parties and shall not be construed against either Party.

**Other Customary
Terms**

The Agreement will contain such terms and conditions as the Parties may reasonably agree and as are customary for transactions of this nature, including, without limitation, indemnification provisions and customary warranties and representations by the Parties.

[remainder of page intentionally left blank]

Cadence Pharmaceuticals, Inc.

By /s/ William R. LaRue
Name: William R. LaRue
Title: Sr. Vice President and CFO

SCR Pharmatop

By /s/ Dietlin
Name: Dietlin
Title: General Manager

Sandoz Inc.

By /s/ Pearl Siew
Name: Pearl Siew
Title: VP & Head, IP US

Sandoz AG

By /s/ Georg Rieder
Name: Georg Rieder
Title: Chief Financial Officer, Sandoz AG

Neogen International N.V.

By /s/ Eric DuBois
Name: Eric DuBois
Title: Managing Director

APC Pharmaceuticals, LLC

By /s/ John F. Kiley
Name: John F. Kiley
Title: Managing Director

By /s/ Andreas Eggmann
Name: Andreas Eggmann
Title: Head Sandoz AG

EXHIBIT A

**NOTICE OF SELECTIVE WAIVER OF
ANY OFIRMEV® PEDIATRIC OR OTHER EXCLUSIVITY**

[Insert Date]

CONFIDENTIAL

**REQUEST FOR EXPEDITED
SELECTIVE WAIVER OF ANY
PEDIATRIC OR OTHER EXCLUSIVITY**

_____, Director
Office of Generic Drugs
CDER
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

_____, Director
Office of New Drugs
CDER
Food and Drug Administration
Rockville, MD 20855-2773

Cadence Pharmaceuticals, Inc. NDA No. 22-450 for OFIRMEV® (acetaminophen) Injection, 1000 mg/100 ml

Sandoz Inc. ANDA No. 204052 for Acetaminophen Injection, 1000 mg/100 ml

**REQUEST FOR EXPEDITED SELECTIVE WAIVER OF PEDIATRIC AND/OR OTHER STATUTORY OR REGULATORY EXCLUSIVITIES
FOR OFIRMEV® (ACETAMINOPHEN) INJECTION, 1000 MG/100 ML, IN FAVOR OF SANDOZ INC.**

Dear _____:

Reference is made to Cadence Pharmaceuticals, Inc.'s ("Cadence's") NDA No. 22-450 for OFIRMEV® (acetaminophen) Injection, 1000 mg/100 ml, and any associated pediatric and/or other statutory or regulatory exclusivities, which are listed in the Orange Book in connection with the above-referenced NDA. Reference is also made to the above-referenced ANDA No. 204052 for Acetaminophen Injection, 1000 mg/100 ml, held by Sandoz Inc. ("Sandoz").

The purpose of this correspondence is to notify the Agency that Cadence has granted a license to Sandoz to market its Acetaminophen Injection product under ANDA No.

204052 as of December 6, 2020, or upon an earlier date in certain circumstances. Pursuant to the terms of the license, Cadence also granted to Sandoz a selective and limited waiver, as of December 6, 2020, or such earlier date as provided under the license, of any unexpired periods of pediatric and/or other statutory or regulatory exclusivities that might be listed in the Orange Book in connection with NDA No. 22-450 for OFIRMEV® (acetaminophen) Injection, 1000 mg/100 ml, with respect to the above-referenced ANDA No. 204052 held by Sandoz for Acetaminophen Injection, 1000 mg/100 ml. The terms of the license are not intended to prohibit Sandoz from maintaining any "Paragraph IV Certifications" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (including as amended or replaced) or pursuant to 21 C.F.R. § 314.94(a)(12) (including as amended or replaced) contained in ANDA No. 204052 for Acetaminophen Injection, 1000 mg/100 ml.

Accordingly, Cadence hereby selectively waives its right to any unexpired periods of pediatric and/or other statutory or regulatory exclusivities listed in connection with NDA No. 22-450 and OFIRMEV® (acetaminophen) Injection, 1000 mg/100 ml, as of December 6, 2020, or such earlier date as provided in the license, as such exclusivities would otherwise apply to Sandoz's ANDA No. 204052 for Acetaminophen Injection, 1000 mg/100 ml.

The Agency's prompt attention to this matter is requested and appreciated. If there are any questions regarding this correspondence, please contact the undersigned at _____.

Sincerely,

CADENCE PHARMACEUTICALS, INC.

Cc: Sandoz Inc.
FDA Office of Chief Counsel

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements and Prospectuses:

(1) Registration Statements (Form S-3 Nos. 333-173295, 333-170538, 333-161756, 333-158126 and 333-147721) of Cadence Pharmaceuticals, Inc., and

(2) Registration Statements (Form S-8 Nos. 333-171396, 333-163941, 333-138226, and 333-187147) pertaining to the 2006 Equity Incentive Award Plan and 2004 Equity Incentive Award Plan of Cadence Pharmaceuticals, Inc.

of our reports dated February 28, 2014, with respect to the financial statements of Cadence Pharmaceuticals, Inc. and to 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, 2013.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2014

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(s) 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

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

Date: February 28, 2014

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(s) 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

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

Date: February 28, 2014

**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, 2013, 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 February 28, 2014.

/s/ THEODORE R. SCHROEDER

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

/s/ WILLIAM R. LARUE

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

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