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2010
ANNUAL REPORT

May 6, 2011

Dear Fellow Stockholders,

Cadence was started with a singular, unchanging vision, and our commitment remains: to build the leading hospital-focused biopharmaceutical company in North America. By that measure, we made great progress in 2010. In November, we received U.S. Food and Drug Administration (FDA) approval of OFIRMEV™ (acetaminophen) injection, the first and only intravenous formulation of acetaminophen approved in the U.S. OFIRMEV is designed to help physicians safely and effectively manage pain and fever in hospitalized patients. The approval of this product reflects years of hard work by our team and our partners.

Now, a new phase of hard work has begun, and we are optimistic in our ability to meet the challenge.

In January 2011, we launched OFIRMEV with a highly motivated team of 147 hospital sales specialists with an average of over 10 years of hospital sales experience, and 13 field-based medical science liaisons. Hospital medicine is complex. Therefore, serving and supporting hospital customers successfully requires both skill and a deep understanding of their needs. We believe we have a unique capability to commercialize hospital products through the development of marketing and sales teams with broad experience in the hospital setting and strong track records of success.

Looking ahead to 2011, we will continue our focus on ensuring rapid formulary adoption and increasing demand for OFIRMEV. We are extremely pleased with the rapid rate at which OFIRMEV has been receiving formulary approvals, which we believe demonstrates a strong desire by hospitals to add OFIRMEV to their formularies and great execution by our sales team. Furthermore, we expect that our significant base of hospital formulary approvals will allow our revenues to accelerate appreciably, particularly in the third and fourth quarters of 2011, as our focus shifts toward pull-through sales.

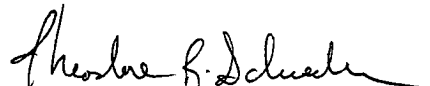
During 2010, we secured a \$30 million credit facility and raised net proceeds of \$93.6 million from the sale of 12.5 million shares of our common stock. We believe that these proceeds will provide the capital essential for a successful national launch of OFIRMEV.

Operationally, to support our business goals, we successfully negotiated agreements with major wholesalers and group purchasing organizations, and ensured that sufficient quantities of OFIRMEV were manufactured in order to fill our supply chain in preparation for the launch of this product. Additionally, as a complement to our existing supply arrangement for OFIRMEV, we executed a supply agreement with a second contract manufacturer. This additional manufacturing facility was approved to supply OFIRMEV to the U.S. marketplace in March 2011.

While focusing on the approval and launch of OFIRMEV, we also achieved a significant business development objective that we believe will position our company for continued long term growth. In June 2010, we signed an exclusive option agreement that gives us the right to acquire Incline Therapeutics, Inc., a privately held specialty pharmaceutical company. Incline is developing IONSYS™ (fentanyl iontophoretic transdermal system), a late stage clinical product candidate intended to provide patient-controlled pain management in hospitals for patients requiring opioids following surgery.

We are pleased with the major accomplishments our company has made during the past year and we remain focused on making OFIRMEV a commercial success. On behalf of the employees and Board of Directors of Cadence, I would like to express our sincere appreciation for your continuing support of our company, and to assure you that we will continue to focus diligently on the path ahead.

Sincerely,

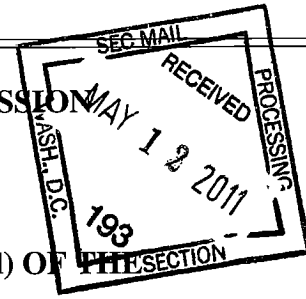


Theodore R. Schroeder
President and Chief Executive Officer

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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, 2010

or

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

Commission File Number 001-33103

CADENCE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

41-2142317
(I.R.S. Employer
Identification No.)

12481 High Bluff Drive, Suite 200
San Diego, California 92130
(858) 436- 1400

(Address, including zip code, and telephone number, including area code, of principal executive offices)

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

Common Stock, \$0.0001 par value per share
(Title of class)

NASDAQ Global Market
(Name of exchange on which registered)

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

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

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

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

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

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

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2010, the last business day of the Registrant's second fiscal quarter, reported on the NASDAQ Global Market, was approximately \$122,170,000. 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 28, 2011, there were 63,148,298 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 2011 Annual Meeting of Stockholders, which is scheduled to be held on June 15, 2011. 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, 2010.

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.

CADENCE PHARMACEUTICALS, INC.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2010

Table of Contents

PART I

| | | |
|----------|---------------------------------|----|
| Item 1. | Business | 1 |
| Item 1A. | Risk Factors | 19 |
| Item 1B. | Unresolved Staff Comments | 42 |
| Item 2. | Properties | 42 |
| Item 3. | Legal Proceedings | 43 |
| Item 4. | (Removed and Reserved) | 43 |

PART II

| | | |
|----------|--|----|
| Item 5. | Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 44 |
| Item 6. | Selected Financial Data | 46 |
| Item 7. | Management's Discussion and Analysis of Financial Condition and Results of Operations | 47 |
| Item 7A. | Quantitative and Qualitative Disclosures About Market Risk | 59 |
| Item 8. | Financial Statements and Supplementary Data | 61 |
| Item 9. | Changes in and Disagreements with Accountants on Accounting and Financial Disclosure | 89 |
| Item 9A. | Controls and Procedures | 89 |
| Item 9B. | Other Information | 90 |

PART III

| | | |
|----------|--|----|
| Item 10. | Directors, Executive Officers and Corporate Governance | 91 |
| Item 11. | Executive Compensation | 91 |
| Item 12. | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 91 |
| Item 13. | Certain Relationships and Related Transactions, and Director Independence | 91 |
| Item 14. | Principal Accounting Fees and Services | 91 |

PART IV

| | | |
|----------|---|----|
| Item 15. | Exhibits, Financial Statement Schedules | 92 |
|----------|---|----|

SIGNATURES

| | |
|------------------|----|
| Signatures | 96 |
|------------------|----|

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PART I

Item 1. *Business*

Company Overview

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

We believe that OFIRMEV fills significant unmet medical needs and that the hospital pharmaceuticals market is both concentrated and underserved. We have established a hospital-focused sales force to promote OFIRMEV to this market, along with any other product candidates we may acquire in the future. We intend to build a leading franchise in the hospital setting, continuing to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations.

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

We own or have rights to various trademarks, copyrights and tradenames used in our business, including the following: *Cadence*®, *OFIRMEV*™ and the *OFIRMEV*™ logo. This report also contains trademarks of others, including *Caldolor*®, *DepoDur*®, *IONSYS*™, *Percocet*®, *Perfalgan*®, *Toradol*®, *Tylenol*®, *Tylenol Codeine 3 McNeil*®, *Ultram*®, and *Vicodin*®.

Our Business Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of proprietary pharmaceuticals principally for use in the hospital setting. Our near-term strategy is to work directly with physicians and hospitals to increase demand for OFIRMEV and ensure formulary adoption. Longer-term, our strategy is to in-license, acquire, develop and commercialize additional product candidates that are in late-stages of development, currently commercialized outside the U.S. or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations. Specifically, we intend to:

- *Successfully expand the sales of OFIRMEV.* We are working to gain formulary adoption at hospitals throughout the U.S., which we believe is an important step toward the broad market adoption of OFIRMEV. Our sales force is equipped with promotional materials and our medical science liaisons with medical education materials to inform and educate hospital-based physicians who treat patients with mild to severe pain and fever. We have entered into agreements with the three major pharmaceutical wholesalers to supply OFIRMEV across the U.S. through their distribution centers.

- *Build a highly leverageable sales organization targeting hospitals.* As of February 28, 2011, we had established a sales force of 147 hospital sales specialists that is focused on promoting OFIRMEV to hospitals in the U.S. Because the number of institutions comprising the hospital marketplace is relatively limited, we believe that we can successfully promote OFIRMEV with our own sales force by focusing on the relatively small number of these institutions that account for a substantial portion of the prescribing activity. The concentrated nature of this market creates the opportunity for significant marketing synergies, and we intend to ultimately leverage our sales force with multiple products across multiple therapeutic categories in the hospital. Outside the U.S., we intend to establish strategic partnerships for the commercialization of any product candidates we may acquire in the future, in areas where we have commercialization rights.
- *Expand our product portfolio through acquiring or in-licensing additional late-stage, hospital-focused products with well-understood risk profiles.* In June 2010, we entered into an option agreement that granted us an exclusive, irrevocable option to purchase Incline Therapeutics, Inc., or Incline, which is developing IONSYS™ (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery. We will seek additional opportunities to acquire or in-license products to continue to exploit our commercial and development capabilities. We believe that our focus on the hospital market enables us to evaluate a broad range of products across multiple therapeutic areas for possible acquisition. To reduce the time to market and the risks and costs of clinical development, we will continue to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations.
- *Pursue additional indications and commercial opportunities for OFIRMEV and future product candidates.* We will seek to maximize the value of OFIRMEV and any other product candidates we may in-license, acquire or develop. These activities may include pursuing additional indications and commercial opportunities for OFIRMEV and any other product candidates we may acquire.

Commercialization Strategy

We believe that we can achieve our strategic goals by deploying our experienced sales organization, supported by a team of field-based medical science liaisons and our internal marketing infrastructure, to promote our products to hospitals that have the greatest use of pharmaceutical products. We will consider opportunities to partner OFIRMEV, along with any other product candidates we may acquire in the future, to reach markets outside the U.S. or to expand our reach to other physician groups outside the hospital setting, where applicable.

The U.S. Hospital Market

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

U.S. hospitals accounted for approximately \$52 billion or 14% of U.S. pharmaceutical sales in 2010, according to Wolters Kluwer Pharma Solutions, an independent marketing research firm. Furthermore, we believe pharmaceutical sales to acute care hospitals are highly concentrated among a relatively small number of large institutions. For example, 1,800 to 1,900 of the approximately 7,000 acute care hospitals in the U.S. represent approximately 80% of hospital injectable analgesic sales. The concentration of high-prescribing institutions enables effective promotion of pharmaceuticals utilizing a relatively small, dedicated sales and marketing organization. We believe the relative lack of promotional efforts directed toward the highly concentrated hospital marketplace makes it an underserved and compelling opportunity, especially for a biopharmaceutical company commercializing its products directly through its own dedicated sales force.

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

Formulary Adoption

We believe an important initial step to broad market acceptance for OFIRMEV is being approved for addition to hospitals' lists of approved drugs, or formulary lists. Prior to the commercial launch of OFIRMEV, we profiled approximately 900 key institutions, which we believe represent approximately half of the target market opportunity for OFIRMEV, to identify the formulary process and the key decision makers. We found that in general, the process for adding a new medication, such as OFIRMEV, to hospital formularies begins with an institution's Pharmacy and Therapeutics Committee, or P&T committee. The P&T committee is the nucleus of the decision making process and can consist of up to 10-20 professionals, including members of various hospital disciplines. They generally meet on a monthly or bimonthly basis to review drugs and medication guidelines. Once a request is made to add a medication to a formulary, it can take anywhere between one and twelve months to schedule the meeting. On average, a company like ours will have several interactions with committee members prior to formulary acceptance, providing information and answering questions that may arise during the committee's deliberations. We expect that the primary tools that support our conversations with P&T committees regarding OFIRMEV are the clinical data that support our claims of significant pain relief, decreased opioid consumption and improved patient satisfaction. Additionally, we can provide P&T committee members with published clinical studies of IV acetaminophen, which may be useful to the committees in their evaluation of the clinical benefits and potential hospital cost savings. After a drug, such as OFIRMEV, is approved on hospital formularies, it may require additional time for the hospital to order the product and incorporate it into its systems and procedures to allow broad use by physicians. We anticipate sales for OFIRMEV will accelerate once it becomes broadly available to physicians.

Sales and Marketing

As of February 28, 2011, we had established a sales force of 147 hospital sales specialists that is supported by 13 field-based medical science liaisons and an experienced commercial management, marketing and sales operations team.

The primary target audience for OFIRMEV will include anesthesiologists and surgeons. Other targets will include certified registered nurse anesthetists, emergency medicine physicians, intensivists, internists, obstetricians and other physicians throughout the hospital. Our commercial sales force will focus on reaching the top 1,800 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 16 years of pharmaceutical industry experience, and an average of seven 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 OFIRMEV formulary adoption and utilization. Because our clinical studies of OFIRMEV have been conducted across a wide range of surgical procedures, we believe that providing access to this data and the unique characteristics of OFIRMEV 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.

Sales Performance of Intravenous Acetaminophen in Europe

Intravenous acetaminophen is marketed by BMS outside of the U.S. and Canada under the brand name Perfalgan. This product is currently approved in approximately 80 countries and is marketed throughout Europe and other parts of the world. Intravenous acetaminophen was launched on a country-by-country basis, beginning in France in 2002, followed by Germany and Spain in 2003, and Italy and the United Kingdom in 2004. Based on 2009 data from IMS Health, Inc., or IMS, an independent marketing research firm, we estimate that more than 440 million doses of intravenous acetaminophen have been distributed since the introduction of this product in Europe, and it has become the market and unit share leader among injectable analgesics, with approximately 87 million units sold, or approximately \$232 million in product sales, in 2009. This performance corresponds to an estimated market share in Europe in 2009 of 22% of all injectable analgesic units, and an estimated 47% market share of all injectable analgesic dollar sales. In some European Union, or E.U., countries, such as France and Belgium, intravenous acetaminophen has a unit market share greater than 40% based on 2009 data from IMS. We believe these and other countries are utilizing intravenous acetaminophen as the foundation for multi-modal analgesia, particularly in the post-operative setting.

U.S. Market Opportunity

We believe that the U.S. IV analgesic market is comparable to the European market when viewed from the perspective of the number of days of analgesic therapy administered to patients annually. The European IV analgesic therapy market consists of intravenous opioids, NSAIDs, a COX-2 inhibitor and acetaminophen. There are multiple intravenous NSAIDs, a COX-2 inhibitor, as well as other intravenous opioids, that are available in Europe that are not available in the U.S. Based on market research conducted by PharmaSavvy, Inc. in Europe in 2009, 78% of inpatients who received intravenous analgesics post-operatively were given intravenous acetaminophen either alone or in combination with other drugs.

Prior to the commercial launch of OFIRMEV in January 2011, the U.S. IV analgesic therapy market consisted of opioids, such as morphine, meperidine, hydromorphone and fentanyl, and two NSAIDs. These two NSAIDs, Toradol (ketorolac tromethamine), a generic form of which is also available in the U.S. from a number of manufacturers, and Caldolor (ibuprofen), represented the only non-opioid IV analgesics available for treating acute pain in adults in the U.S. prior to OFIRMEV. According to Wolters Kluwer Pharma Solutions, approximately 270 million vials of injectable analgesics were sold in the U.S. in 2010. In response to a market survey of more than 100 surgeons and anesthesiologists conducted by PharmaSavvy in the U.S. prior to the approval of OFIRMEV, doctors indicated that they would be likely to use intravenous acetaminophen post-operatively in approximately 70% of inpatient surgeries.

On average, pharmaceutical pricing continues to be higher in the U.S. than in Europe. According to IMS, the average selling price in Europe in 2009 was approximately \$2.66 (U.S. dollars) per vial of Perfalgan, or intravenous acetaminophen. We believe the unit price of Perfalgan in major European countries was largely driven by government-controlled reference pricing in those markets. In Scandinavian countries with less restrictive pricing controls, the average Perfalgan selling price is as high as \$9.80 (U.S. dollars) per vial. The price of ketorolac in the U.S. in 1997, prior to the entry of generic competitors, was approximately \$7.00 (U.S. dollars) per vial, according to the American Journal of Health-System Pharmacy. The price of Caldolor in the U.S. was \$10.50 (U.S. dollars) per 800 mg vial in 2010. We have set the list price, or wholesale

acquisition cost, of OFIRMEV at \$10.75 per vial and we expect the net realized price to us, net of rebates, chargebacks, discounts, returns and the like, will be approximately \$10.05 per vial. We have signed agreements with the five largest group purchase 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 will drive the adoption of OFIRMEV in the U.S. include the efficacy and safety profile of OFIRMEV 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 need for a more convenient dosage form for patients unable to take medication orally.

Marketed Product

OFIRMEV™ Product Overview

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

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 are unable to take medications by mouth, require faster onset of pain relief or fever reduction, or for whom it is otherwise more convenient to receive an injectable analgesic.

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

Pain Management

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

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

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

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

Other than OFIRMEV, the only non-opioid intravenous analgesics currently available in the U.S. are the NSAIDs Toradol (ketorolac tromethamine), a generic form of which is also available in the U.S. from a number of manufacturers, and Caldolor (ibuprofen), which was approved by the FDA in mid-2009 for the treatment of mild to moderate pain in adults, and moderate to severe pain in adults as an adjunct to opioid therapy. Caldolor is not approved for pediatric use, and ketorolac is only approved for use as a single dose in children greater than two years of age. NSAIDs act as non-selective inhibitors of the enzyme cyclooxygenase, inhibiting both the cyclooxygenase-1, or COX-1, and cyclooxygenase-2, or COX-2, enzymes. Since NSAIDs do not produce respiratory depression or impair gastrointestinal motility, they are considered to be useful alternatives or adjuncts to opioids for the relief of acute pain.

However, the use of NSAIDs is limited in the post-operative period due to their potential to cause adverse effects. NSAIDs such as ketorolac and ibuprofen exert a direct inhibitory effect on platelet aggregation, which could result in increased bleeding susceptibility in the post-operative setting. These NSAIDs are often avoided in surgical patients because they may be associated with renal toxicity, particularly in patients with compromised renal function or hypoperfusion. NSAIDs may also be associated with gastric irritation and gastric bleeding, and an increased incidence of cardiovascular adverse events have been found to be associated with postoperative use of certain NSAIDs. All NSAIDs carry a boxed warning for a number of side effects. A boxed warning is the strongest type of warning that the FDA can require for a drug and is generally reserved for situations where prescribers should be aware of the potential for adverse drug reactions that can cause serious injury or death.

Multi-Modal Pain Management

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

The concept of using acetaminophen for multi-modal management of pain to improve pain relief and reduce opioid consumption is not new to physicians. In fact, oral acetaminophen-opioid combination products are very commonly prescribed for the treatment of acute pain, including post-operative pain. Such products include

Vicodin (hydrocodone plus acetaminophen), Percocet (oxycodone plus acetaminophen), Tylenol Codeine #3 McNeil (codeine plus acetaminophen), and Ultram (tramadol plus acetaminophen). Approximately 73% of the 14.4 billion doses of oral opioids sold in the U.S. in 2008 were combination products that included acetaminophen. As the only IV formulation of acetaminophen available in the U.S., OFIRMEV provides the only option to extend this common multi-modal approach to the peri-operative setting, when patients are unable to take oral medications.

Fever Reduction

Fever is an increase in internal body temperature above its average normal value. A significant fever is usually defined as an oral temperature of greater than 100.4 degrees Fahrenheit (38 degrees Centigrade). Fever is typically a sign of the body's response to an underlying infection, disease process or allergic reaction. Very high fevers may cause hallucinations, confusion, irritability, convulsions or death.

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

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

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

Treating fever in a hospitalized patient with oral medication may be difficult or not feasible due to the severe nausea and vomiting that often accompany a high fever, or because the patient is unconscious, sedated, fasting or experiencing gastrointestinal dysfunction. Oral medications are also precluded in patients on a restricted oral intake regimen due to a concomitant medical condition or upcoming medical procedure. In the U.S., OFIRMEV is the only available intravenous form of acetaminophen, and aspirin is currently not available in intravenous dosage forms. While rectal delivery of these medications is sometimes possible, drug absorption using this method may be highly variable, resulting in the potential for inadequate levels of efficacy. Rectal delivery is further complicated if the drug is expelled with a bowel movement, which leads to difficulty determining the amount of medication delivered.

Therapeutic drug levels often may be achieved more rapidly when a drug is administered intravenously compared to oral or rectal administration, offering the potential advantage of a more rapid onset of action. This may be particularly desirable in patients with high fever, or in whom fever is causing undesirable symptoms or complications such as febrile seizures. It may also be more convenient to administer medications in an intravenous dosage form, particularly for patients who currently have an intravenous line in place. While Caldolor (intravenous ibuprofen) is approved for the treatment of fever in adults, it has not been approved for the treatment of fever in children. We believe that the availability of OFIRMEV in the U.S. offers a significant new 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 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 showed a greater reduction in pain intensity over 24 hours (SPID24) compared to placebo ($P < 0.001$).
- *Morphine Consumption.* OFIRMEV 1 g + PCA morphine significantly reduced morphine consumption vs. placebo + PCA morphine alone (-46% after first dose, $P < 0.01$; -33% over 24 hours, $P < 0.01$). Median time to first rescue medication was significantly longer with OFIRMEV 1 g compared with placebo (3 hours vs. 0.8 hours, $P = 0.0001$). The clinical benefit of reduced opioid consumption was not demonstrated.
- *Patient Satisfaction.* Patients' global evaluation of study treatment (excellent plus good scores) significantly favored the OFIRMEV group over PCA morphine alone (40.8% vs. 23.1%, $P = 0.004$). There were no differences between OFIRMEV and placebo groups in incidence of adverse events. No serious hepatic events were related to treatment with OFIRMEV 1 g. The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients

Adult Pain Study 2, Cadence Study 304

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

- *Pain Intensity.* A significantly greater reduction in pain intensity differences from baseline was seen with OFIRMEV 1 g compared to the combined placebo group over the 24-hour period ($P = 0.0068$). Time to

meaningful pain relief after the first dose was significantly shorter in subjects who received OFIRMEV 1 g compared to the matched placebo group, with median values of 24.9 minutes and 53.9 minutes, respectively (P=0.0028). Similarly, there was a significant difference in pain intensity differences from baseline seen with OFIRMEV 650 mg compared with the combined placebo group over 24 hours (P=0.0183).

- *Morphine Consumption.* No statistical differences were found between OFIRMEV 1 g or 650 mg and the combined placebo groups in total rescue medication consumption or in the first time to rescue medication.
- *Patient Satisfaction.* Patient global evaluation of study treatment (excellent plus good scores) significantly favored OFIRMEV 1 g over the control group (P=0.0004).

Adult Fever Study 1, Cadence Study 302

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

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

Post-Approval Commitments

In accordance with a Pediatric Research Equity Act requirement included in the NDA approval of OFIRMEV, we will conduct a post-marketing efficacy study of OFIRMEV in infants and neonates. In addition, we plan to use the data from this study to satisfy a formal written request from the FDA under Section 505A of the U.S. Food, Drug and Cosmetic Act that was made as part of the approval process for OFIRMEV. 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. No additional commitments were assigned to us by the FDA in connection with the approval of the NDA for OFIRMEV.

Competition

The pharmaceutical industry is subject to intense competition and characterized by extensive research efforts and rapid technological progress. Competition in our industry occurs on a variety of fronts, including developing and bringing new products to market before others, developing new technologies to improve existing products, developing new products to provide the same benefits as existing products at lower cost and developing new products to provide benefits superior to those of existing products. There are many companies, including generic manufacturers as well as large pharmaceutical companies, that have significantly greater financial and other resources than we do, as well as academic and other research institutions that are engaged in research and development efforts for the indications targeted by our product.

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

Injectable Opioids

- morphine, the leading product for the treatment of acute post-operative pain, a generic version of which is available from several manufacturers;

- DepoDur, an extended release injectable (epidural) formulation of morphine; and
- other injectable opioids; including fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers.

Injectable NSAIDs

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

Product Candidates

Competitors may seek to develop alternative formulations of intravenous acetaminophen for our targeted indications that do not directly infringe on our in-licensed patent rights. We are aware of several third-party U.S. and Canadian patents and patent applications directed to various potential injectable formulations of acetaminophen, including intravenous formulations, as well as methods of making and using these potential formulations. We are also aware of a number of product candidates in development to treat acute pain, including injectable NSAIDs, novel opioids, new formulations of currently available opioids, long-acting local anesthetics and new chemical entities as well as alternative delivery forms of various opioids, COX2 inhibitors, and NSAIDs. A variety of pharmaceutical and biotechnology companies are developing these new product candidates, including but not limited to Acusphere, Inc., Anesiva, Inc., Cara Therapeutics, Inc., Cephalon, Inc., Durect Corporation, Javelin Pharmaceuticals, Inc., NeurogesX, Inc., Pacira Pharmaceuticals, Inc., Paion AG, St. Charles Pharmaceuticals, Inc., and TheraQuest Biosciences, LLC.

Business Relationships

Licensing Agreement with Bristol-Myers Squibb Company

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

As consideration for the license, we paid a \$25.0 million up-front fee and an additional \$15.0 million fee in November 2010 after approval of the product. In addition, we may be required to make future milestone payments totaling up to \$25.0 million upon the achievement of various milestones related to achievement of certain net sales levels of OFIRMEV. We are also obligated to pay a royalty on net sales of the product. We have the right to grant sublicenses to our affiliates.

The term of the OFIRMEV agreement generally extends on a country-by-country basis until the last licensed patent expires, which is expected to occur in the U.S. in 2021. Either party may terminate the OFIRMEV agreement upon delivery of written notice if the other party commits a material breach of its obligations and fails to remedy the breach within a specified period or upon the occurrence of specified bankruptcy, reorganization, liquidation or receivership proceedings. In addition, BMS may terminate the OFIRMEV agreement if we breach, in our capacity as a sublicensee, any provision of the agreement between BMS and Pharmatop. The OFIRMEV agreement will automatically terminate in the event of a termination of the license agreement between BMS and Pharmatop. We may terminate the OFIRMEV agreement at any time upon specified written notice to BMS after the occurrence of events of default that relate to our territory and would entitle BMS to terminate the Pharmatop license agreement. The events of default include Pharmatop's inability to maintain specified claims under listed patents, the marketing by a third party of a parenterally-administered product containing acetaminophen, subject to certain conditions, or a successful third party action that deprives Pharmatop of its rights to specified patents. We may also terminate the OFIRMEV agreement upon specified written notice after an uncured failure by Pharmatop to perform any of its material obligations under the Pharmatop license agreement with respect to our territory that would permit BMS to terminate the Pharmatop license agreement.

Either BMS or Pharmatop may terminate the license agreement between them upon delivery of written notice after an uncured failure by the other party to perform any of its material obligations under the license

agreement. BMS may generally terminate the agreement upon written notice to Pharmatop within a specified period so long as all payments due under the agreement to Pharmatop are current. Pharmatop may terminate the agreement upon specified written notice if BMS opposes any of the listed patent applications or challenges the validity or enforceability of any of the listed licensed patents. BMS is also entitled to terminate the Pharmatop agreement upon the occurrence of events of default that relate to the territory described above.

Option Agreement with Incline Therapeutics, Inc.

On June 21, 2010, we entered into an option agreement with Incline, a privately held specialty pharmaceutical company, pursuant to which we obtained an exclusive, irrevocable option to acquire Incline. Incline is developing IONSYS (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery. IONSYS is a compact, needle-free, self-contained, pre-programmed system designed to be applied to the skin on the upper arm or chest and activated by patients double clicking a button on the system. A generally imperceptible electrical current then actively delivers a small dose of the short-acting opioid analgesic fentanyl directly through the skin and into the systemic circulation. IONSYS was approved by both the FDA and the European Medicines Agency, or EMA, in 2006. The product was launched in Europe, but was withdrawn from the market by Incline's licensor in 2008 as a precautionary measure, and is not currently marketed anywhere in the world. Incline must obtain regulatory approval from the FDA for new patient safety features being developed into the system before it can market IONSYS in the U.S., and Incline must obtain regulatory approvals from comparable regulatory authorities before marketing IONSYS in other countries. Incline expects to submit a supplemental NDA to the FDA in 2013.

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

In consideration for the option to acquire Incline, we paid Incline a \$3.5 million upfront option fee and we will pay Incline a second \$3.5 million fee upon Incline receiving the second tranche of its Series A financing if we have not yet exercised our option to acquire Incline. During the first option period, we may acquire Incline for an amount not to exceed \$135.0 million. During the second option period, we may acquire Incline for an amount not to exceed \$228.0 million, plus payment of an additional amount not to exceed \$57.0 million upon FDA approval of IONSYS.

The first option period, which commenced on June 21, 2010, extends through the later to occur of (1) 12 months or (2) one day prior to the date on which Incline receives the second tranche of its Series A financing. The second option period commences on the expiration of the first option period and extends until the earliest to

occur of (a) 30 days after the date on which Incline submits a supplemental NDA for IONSYS to the FDA, (b) 30 days after the filing of an initial public offering by Incline, or (c) 42 months. We have an exclusive right of first negotiation to acquire Incline for the six-month period following the expiration of the second option period and may elect to extend the second option period for two additional three-month periods upon the payment of \$2.5 million to Incline for each period. During the option periods, Incline will remain primarily responsible for the development of IONSYS. However, we and Incline have formed a joint development committee to oversee the global development and regulatory approval for the IONSYS product candidate.

Development and Supply Agreement with Baxter Healthcare Corporation

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

Pursuant to the terms of the agreement with Baxter, we will pay Baxter a per unit purchase price based on the amount of finished OFIRMEV drug product produced, which price will be increased annually, and may be adjusted to reflect an increase or decrease, as the case may be, in the cost of material required to manufacture OFIRMEV, subject to specified limitations. We are obligated to purchase a minimum number of units of OFIRMEV each year or pay Baxter an amount equal to the purchase price multiplied by the shortfall in units. In addition, Baxter will be our primary supplier of OFIRMEV up to a specified number of units in each year, subject to Baxter's ability to timely supply the specified volumes required by us. However, if Baxter fails or declines to supply a sufficient quantity of OFIRMEV in accordance with our purchase orders during a specified period of time, then we may purchase that OFIRMEV from third party suppliers and such quantity will be deducted from the quantity of OFIRMEV that we otherwise would have been required to purchase from Baxter. We are also obligated to reimburse Baxter for all reasonable costs directly related to work performed by Baxter in support of any change in the active pharmaceutical ingredient, or API, source or API manufacturing process.

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

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

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

Supply Agreement with Lawrence Laboratories, Inc.

In addition, in December 2010, we entered into an agreement with Lawrence Laboratories, an indirect wholly-owned subsidiary of BMS to be a supplemental source for OFIRMEV. Bristol-Myers Squibb Srl, or BMS Anagni, an indirect subsidiary of BMS located in Anagni, Italy, will manufacture OFIRMEV on behalf of Lawrence Laboratories. BMS Anagni also currently manufactures intravenous acetaminophen for sale and distribution by BMS and its affiliates in a number of countries outside of the U.S. and Canada. We submitted a supplemental NDA to the FDA in December 2010 seeking the approval of the BMS Anagni facility as an additional manufacturing site for OFIRMEV. We anticipate that a successful completion of an FDA inspection of the BMS Anagni facility will be required prior to approval of the submission, and we estimate a four to six-month review period from the time of submission. We anticipate that the FDA will inspect the BMS Anagni facility in the first quarter of 2011. We believe that the geographic diversification of our manufacturing operations afforded by the arrangement with Lawrence Laboratories supports our corporate risk management objectives.

Distribution and Wholesaler Agreements

We distribute OFIRMEV primarily to drug wholesalers, who in turn distribute the product to hospital pharmacies and other institutional customers. We have retained third-party service providers to perform a variety of functions related to the distribution of OFIRMEV, including warehousing, customer service, order-taking, invoicing, collections, shipment and returns processing. We have entered into agreements with the three major pharmaceutical wholesalers for distribution management services and data reporting in exchange for a fee.

Intellectual Property

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

Research and Development

Our research and development expenses were \$13.8 million in 2010, \$19.5 million in 2009 and \$40.0 million in 2008. Our historical research and development expenses relate predominantly to OFIRMEV and our discontinued omiganan pentahydrochloride product candidate. Our research and development expenses consist primarily of salaries and related employee benefits for our research and development team, license fees paid to our licensors prior to approval of our drug candidates, pre-commercialization manufacturing development activities, costs associated with clinical trials, and costs associated with non-clinical activities, such as expenses related to regulatory submissions. License fees are paid to the patent holders of our product candidates that give us the exclusive licenses to the patent rights and know-how for selected indications and territories. Manufacturing development activities include the costs to develop facilities for the commercial production of our drug products prior to approval, the production of supply and validation lots, and other manufacturing support activities related to the requirements for submitting NDAs for our product candidates. The clinical trial expenses include payments to vendors such as clinical research organizations and investigator sites, clinical suppliers and related consultants.

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

development resources. Therefore, we are unable to estimate with any certainty the costs we will incur in completing our development efforts for OFIRMEV or any other product candidate we might acquire or in-license.

Government Regulation

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

FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

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

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

The applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the policies agreed to by the FDA under PDUFA, the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the

FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA's evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA and issue a complete response letter.

Section 505(b)(2) New Drug Applications

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

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

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

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

Fast Track Designation

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

The Hatch-Waxman Act

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

Other Regulatory Requirements

FDA Post-Approval Regulatory Requirements

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

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

Adverse experiences associated with use of the products must be reported to the FDA, and FDA rules govern how we can label, advertise or otherwise commercialize our products. There are current post-marketing

safety surveillance requirements that we will need to meet to continue to market an approved product. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

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

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

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

Other Government Regulatory Requirements

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

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

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, and several states have enacted laws affecting pharmaceutical marketing and advertising practices, including laws affecting interactions with health care professionals. States may require, and the PPACA will require, pharmaceutical manufacturers to report their

sales and marketing expenses, which may include payments to health care professionals. States may also require compliance with a marketing code of conduct and require certification of compliance with such code be submitted to a state agency or a posted on the pharmaceutical company's website. Companies must also be registered or licensed by the federal and state governments prior to manufacturing or distributing prescription drug products.

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

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

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

Third-Party Reimbursement and Pricing Controls

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

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

Employees

As of February 28, 2011, we had 247 employees. Of these, 28 employees were engaged in clinical research, regulatory, quality assurance and product manufacturing, 196 employees were in sales, marketing, commercial operations, medical affairs and business development and 23 employees were in administration and finance.

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this report, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Business and Industry

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

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

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

- create market demand for OFIRMEV through our own marketing and sales activities, and any other arrangements to promote this product we may later establish;
- train, deploy and support a qualified sales force;
- secure formulary approvals for OFIRMEV at a substantial number of targeted hospitals;
- procure a supply of OFIRMEV from our third-party manufacturers in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;
- implement and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- ensure that our entire supply chain for OFIRMEV efficiently and consistently delivers OFIRMEV to our customers; and
- maintain and defend our patent protection and regulatory exclusivity for OFIRMEV.

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

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

As OFIRMEV is a newly marketed drug, none of the members of our sales force had ever promoted OFIRMEV prior to its launch in January 2011. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians, nurses, hospitals, and other customers to use OFIRMEV. In addition, we also must train our sales force to ensure that a consistent and appropriate message about OFIRMEV is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of OFIRMEV and its proper administration, our efforts to successfully commercialize OFIRMEV could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

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

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

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

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

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

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

- our sales of OFIRMEV may be lower than expected;
- the costs associated with our efforts to sell, market and distribute OFIRMEV, including costs associated with establishing and maintaining our sales force and commercial infrastructure, may be greater than anticipated;
- we may incur unexpected costs in order to ensure a sufficient supply of OFIRMEV from our contract manufacturers in order to meet customer demand; and
- we may be required to file lawsuits to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of intravenous acetaminophen, 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. For example, in February 2009, we completed a private placement of common stock and warrants to purchase common stock, raising net proceeds of approximately \$86.2 million. In June 2010, we drew an initial advance of \$20.0 million under our loan and security agreement with Oxford Finance Corporation, Silicon Valley Bank and GE Business Financial Services, Inc., and a second advance of \$10.0 million was made in November 2010, following the approval of OFIRMEV by the FDA. In addition, in November 2010, we undertook a public offering of common stock that raised net proceeds of approximately \$93.6 million.

We believe that we currently have sufficient funds to meet our projected operating requirements, at a minimum, through the next twelve months. This estimate does not reflect any exercise of our right to acquire Incline or participation in other strategic transactions. We have based this estimate on assumptions that may prove to be wrong and we could spend our available financial resources faster than we currently expect. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to reduce the scope of or eliminate some or all of our sales, marketing and commercialization efforts for OFIRMEV, which could decrease sales of this product and have a material adverse effect on our financial condition, stock price and operations.

We have no manufacturing capabilities and depend entirely upon our contract manufacturers to produce OFIRMEV. If our contract manufacturers fail to meet our requirements for OFIRMEV, or fail to fully comply with cGMP regulations, we may be unable to meet market demand, and may lose potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We have no such manufacturing capabilities, so we currently rely on Baxter Healthcare Corporation, or Baxter, as our primary source for OFIRMEV.

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

In addition, in December 2010, we entered into an agreement with Lawrence Laboratories, an indirect wholly-owned subsidiary of BMS to be a supplemental source for OFIRMEV. Bristol-Myers Squibb Srl, or BMS Anagni, an indirect subsidiary of BMS located in Anagni, Italy, will manufacture OFIRMEV on behalf of Lawrence Laboratories. BMS Anagni also currently manufactures intravenous acetaminophen for sale and distribution by BMS and its affiliates in a number of countries outside of the U.S. and Canada. We submitted a supplemental NDA to the FDA in December 2010 seeking the approval of the BMS Anagni facility as an additional manufacturing site for OFIRMEV. The successful completion of an FDA inspection of the BMS Anagni facility will be required prior to approval of the submission, and we estimate a four to six-month review period from the time of submission. We anticipate that the FDA will inspect the BMS Anagni facility in the first quarter of 2011. Until the supplemental NDA is approved, Baxter will remain as our sole source of supply for OFIRMEV, and we cannot be sure that supplemental NDA will be approved timely or at all.

Baxter and Lawrence Laboratories must comply with strictly enforced federal, state and foreign regulations, including GMP regulations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or

withdrawal of product approval, and would limit the availability of OFIRMEV. For example, in February 2010, we received a complete response letter from the FDA, which stated that our NDA could not be approved due to deficiencies with respect to good manufacturing practices observed during the agency's inspection of Baxter's facilities. In the event that the FDA inspection of the BMS Anagni facility reveals similar deficiencies, the approval of our supplemental NDA for OFIRMEV could be delayed until any such issues are resolved. 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, product liability claims and litigation.

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

Although we actively manage these third party relationships to ensure continuity and quality, some events beyond our control could result in the complete or partial failure of these goods and services. Any such failure could have a material adverse effect on our financial condition and operations. In addition, as OFIRMEV is a new product, the effect of any delay or failure to deliver could be magnified due to the lack of a sales track record for OFIRMEV in the U.S.

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

We have built our own sales and marketing capabilities in order to market OFIRMEV directly to physicians, nurses, hospitals, group purchasing organizations and other customers, and will continue to incur significant expenses associated with the recruitment, training and compensation of our sales representatives. We expect that the annual sales force cost associated with each of our sales representatives will be approximately \$300,000, but it could be significantly more. The continued development of our hospital-focused sales, marketing and distribution infrastructure for our domestic operations will be expensive and time consuming, and there may be unforeseen costs and expenses or time-delays associated with such activities. If we are not successful in training and managing our sales and marketing personnel, we may not achieve our sales objectives. In addition, if we are unable to establish and maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue, may experience increased expenses, and may never become profitable.

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

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We will continue to face competition in our efforts to market and sell OFIRMEV from other biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render OFIRMEV obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render OFIRMEV obsolete or noncompetitive.

OFIRMEV will compete with well-established products with similar indications. Competing injectable products available for the treatment of pain include opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems. Ketorolac, an injectable NSAID, is also available generically in the U.S. from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, is

available for the treatment of pain and fever in adults. Competing products available for the treatment of fever in the hospital setting include acetaminophen administered orally and rectally, aspirin and NSAIDs, which may be administered orally, topically or intravenously. Additional products may be developed for the treatment of acute pain, including new injectable NSAIDs, novel opioids, new formulations of currently available opioids and NSAIDs, long-acting local anesthetics and new chemical entities, as well as alternative delivery forms of various opioids and NSAIDs.

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

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

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

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

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

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

Our ability to effectively promote and sell OFIRMEV and any other product candidates we may license or acquire in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a reasonable cost, achieve hospital formulary acceptance for the product and sell the product at a competitive price as well as our ability to obtain sufficient third-party coverage or reimbursement. Although the list price, or wholesale acquisition cost, for OFIRMEV is currently \$10.75 per vial and the net realized price to us, net of rebates, chargebacks, discounts, returns, and similar items, is expected to be approximately \$10.05 per vial, this pricing could change and we cannot be sure certain that our pricing will lead to market acceptance. Since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract

customers in the hospital marketplace will also depend on our ability to effectively promote OFIRMEV and any other product candidate to hospitals that are members of group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with OFIRMEV and any other product candidates we may license or acquire. If OFIRMEV, or any other product candidates that are approved, do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits and risks of OFIRMEV or any other product candidates may require significant resources and may never be successful.

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

We rely on third-party service providers to perform a variety of functions related to the sale and distribution of OFIRMEV, key aspects of which are out of our direct control. The services provided by these third parties include warehousing and inventory control, distribution, customer service, accounts receivable management and cash collection. As a result, most of our inventory is stored at a single warehouse maintained by one such service provider. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or if our products encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we have engaged third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding OFIRMEV and related services. If the quality or accuracy of the data maintained or services performed by these third parties is insufficient, we could be subject to regulatory sanctions.

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

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

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

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

- issue warning letters or untitled letters;

- impose consent decrees, which may include the imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose fines other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements;
- exclude us from participating in U.S. federal healthcare programs, including Medicaid or Medicare; or
- seize or detain products or require a product recall.

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

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

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

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

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

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

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

In March 2010, the President signed the PPACA, which makes extensive changes to the delivery of health care in the U.S. The PPACA includes numerous provisions that affect pharmaceutical companies, some of which were effective immediately and others of which will be taking effect over the next several years. For example, the PPACA seeks to expand health care coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA will also impose substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit, an annual fee imposed on all manufacturers of brand prescription drugs in the U.S., and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The PPACA also contains cost containment measures that could reduce reimbursement levels for health care items and services generally, including pharmaceuticals. It also will require reporting and public disclosure of payments and other transfers of value provided by pharmaceutical companies to physicians and teaching hospitals. We cannot predict what effect the PPACA or other healthcare reform initiatives that may be adopted in the future will have on our business. Several lawsuits have been filed challenging the constitutionality of provisions of the PPACA, with varying results. Although it is possible that portions of the PPACA may be repealed or determined to be unconstitutional, other health reform legislation may be implemented. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. In particular, California has enacted legislation that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. California's electronic pedigree requirement is scheduled to take effect in January 2015. Compliance with California and future federal or state electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

Managed care organizations are increasingly challenging the prices charged for medical products and services and, in some cases, imposing restrictions on the coverage of particular drugs. Many managed care organizations negotiate the price of medical services and products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's patient population. The process for obtaining coverage can be lengthy and costly, and we expect that it could take several months before a particular payor initially reviews our product and

makes a decision with respect to coverage. For example, third-party payors may require cost-benefit analysis data from us in order to demonstrate the cost-effectiveness of OFIRMEV or any other product we might bring to market. For any individual third-party payor, we may not be able to provide data sufficient to gain reimbursement on a similar or preferred basis to competitive products, or at all.

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

As a condition of reimbursement by various federal and state healthcare programs, we must calculate and report certain pricing information to federal and state healthcare agencies. The regulations regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates and other governmental programs are complex. Our calculations and methodologies are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. In addition, because our processes for these calculations and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to the risk of errors. Any failure to comply with the government reporting and payment obligations could result in civil and/or criminal sanctions.

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

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

Public concern regarding the safety of drug products such as OFIRMEV could result in new requirements from regulatory agencies to include unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. For example, in January 2011, the FDA issued a press release and posted on its website a drug safety communication asking manufacturers of prescription drug products containing combinations of acetaminophen and opioid medications to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each dosage unit (i.e. each tablet or caplet). In the announcement, the FDA also requested manufacturers to update labels for such products to include a boxed warning highlighting the potential for severe acetaminophen-induced liver injury and a warning

highlighting the potential for allergic reactions. The boxed warning required for affected products reaffirms previous statements made by the FDA that most cases of liver injury are associated with acetaminophen doses that exceed 4,000 mg per day. While the FDA has indicated that this communication does not apply to intravenous acetaminophen, it is possible that the FDA may apply similar labeling requirements to OFIRMEV in the future. Any perception or concern that acetaminophen is unsafe could harm our ability to successfully commercialize and sell OFIRMEV, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, granted significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of that law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials.

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

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

Governments continue to propose and pass legislation designed to reduce the cost of healthcare. In some foreign markets, such as Canada, the government controls the pricing of prescription pharmaceuticals. In these countries, pricing negotiated with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. In the U.S., we expect that there will be an increase in federal and state proposals to implement pricing controls for prescription drugs, and new legislation and regulations affecting the pricing of pharmaceuticals might change before our product candidates are approved for marketing. For example, the U.S. Congress is considering a number of legislative and regulatory proposals with an objective of ultimately reducing healthcare costs. Legislative and regulatory actions under consideration in the U.S. include health care reform initiatives that could significantly alter the market for pharmaceuticals (such as private health insurance expansion, the creation of competing public health insurance plans, a variety of proposals that would reduce government expenditures for prescription drugs to help finance healthcare reform, or the eventual transition of the U.S. multiple payer system to a single payer system). Other actions under consideration include proposals for government intervention in pharmaceutical pricing, changes in government reimbursement, an

accelerated approval process for “follow-on” biologics, legalization of commercial drug importation into the U.S., and involuntary approval of medicines for over-the-counter, or OTC, use. Such legislation could result in the exclusion of OFIRMEV and any other product candidates we may license or acquire from coverage and reimbursement programs, or lower the prices we would receive for our product candidates. Our revenues from the sale of OFIRMEV or any other approved products could be significantly reduced as a result of these cost containment measures and reforms, which would negatively impact our profitability.

If we breach any of the agreements under which we license rights to OFIRMEV from others, we could lose the ability to commercialize OFIRMEV.

In March 2006, we entered into an exclusive license agreement with BMS relating to OFIRMEV for the U.S. and Canada. Because we have in-licensed the rights to this product candidate from a third party, if there is any dispute between us and our licensor regarding our rights under our license agreement, our ability to commercialize this product candidate may be adversely affected. Any uncured, material breach under our license agreement could result in our loss of exclusive rights to OFIRMEV and may lead to a complete termination of our related commercialization efforts.

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

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

We have substantially increased the size of our organization, and we may experience difficulties in managing growth.

As of February 28, 2011, we had 247 employees. The commercial launch of OFIRMEV required us to substantially expand our managerial, commercial, financial and other personnel resources, particularly in sales and marketing positions. For example, in anticipation of the commercial launch of OFIRMEV, we hired 147 sales representatives during the period from November 2010 through January 2011. Our management, personnel, systems and facilities currently in place may not be adequate to support this recent growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses, and the failure to do so could have a significant negative impact on our future product revenues and business results. Our need to effectively manage our operations, growth and various projects requires that we:

- effectively train and manage a significant number of new employees, in particular our hospital sales specialists, who have no prior experience with our company or OFIRMEV, and establish appropriate systems, policies and infrastructure to support our commercial organization;
- ensure that our consultants and other service providers successfully carry out their contractual obligations, provide high quality results, and meet expected deadlines;
- continue to carry out our own contractual obligations to our licensors and other third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

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

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

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

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

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

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

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

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

Although we currently have commercial product liability coverage for OFIRMEV, which includes coverage for any clinical trials we may perform, insurance coverage is becoming increasingly expensive and we may be unable to obtain commercially reasonable product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. Our commercial product liability insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and our operations may be setback.

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

An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on the hospital marketplace. For example, we recently signed an agreement granting us an option to acquire Incline. As part of our efforts to acquire businesses such as Incline, or to in-license products, we conduct technical, business and legal due diligence with the goal of identifying and evaluating material risks involved in such transactions, which may include:

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

Additionally, in connection with any such acquisition or in-licensing transaction, we must estimate the value of the transaction by making certain assumptions about, among other things, likelihood of regulatory approval for unapproved products and the market potential for marketed products and/or product candidates. Ultimately, our

assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of a transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, we might not realize the intended advantages of the acquisition or in-licensing transaction. If we fail to realize the expected benefits from the transactions we have consummated or may consummate in the future, the results of our operations and financial condition could be adversely affected.

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

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

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.

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

We may not have sufficient capital to exercise our option to acquire Incline. If we elect to exercise the option, the payment of up to \$135.0 million during the first option period, or up to \$228.0 million, plus up to \$57.0 million upon FDA approval of IONSYS, during the second option period, would require us to raise additional funds to finance the acquisition. Raising such additional funds or paying up to 50% of the applicable option exercise payment in the form of our common stock would result in the incurrence of additional indebtedness or dilution for our stockholders.

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

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

Risks Related to Intellectual Property

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

The active ingredient in OFIRMEV is acetaminophen. Patent protection for the acetaminophen molecule itself in the territories licensed to us, which include the U.S. and Canada, is not available. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as OFIRMEV so long as the competitors do not infringe any process or formulation patents that we have in-licensed from BMS and its licensor, SCR Pharmatop. We are aware of a number of third-party patents in the U.S. that claim methods of making acetaminophen. If a supplier of the API for our OFIRMEV product candidate is found to infringe any of these method patents covering acetaminophen, our supply of the API could be delayed and we may be required to locate an alternative supplier. We are also aware of several U.S. and Canadian patents and patent applications 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. In addition, while a notice of allowance by the Canadian Patent Office was recently issued with respect to one of the patent applications that we have in-licensed for Canada, another is currently being examined, and may ultimately issue with claims that cover less than the corresponding in-licensed U.S. patents, or simply not issue at all. The commercial opportunity for OFIRMEV could be significantly harmed if competitors are able to develop alternative formulations of acetaminophen outside the scope of our in-licensed patents.

One or more third parties may challenge the patents covering OFIRMEV, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug product containing acetaminophen and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for OFIRMEV; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-party's generic drug product. A 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 certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. 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 receipt of the notice automatically prevents the FDA from approving the third-party's ANDA until the earliest of 30 months or the date on which the patent expires,

the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party, or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action. If a patent infringement lawsuit is not initiated within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products.

We depend on our licensors for the maintenance and enforcement of our intellectual property and have limited control, if any, over the amount or timing of resources that our licensors 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 SCR Pharmatop, or 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 to diligently prosecute the patent applications and maintain any issued patents related to OFIRMEV in Canada. BMS has the opportunity to consult, review and comment on any patent office communications. We may not receive any patent from the applications in Canada, or if patents do issue they may be inadequate to protect our OFIRMEV product from competition.

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

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

Our success will depend in part on our ability to obtain and maintain patent protection for OFIRMEV, both in the U.S. and Canada. While we intend to take actions reasonably necessary to enforce our patent rights, we depend on our licensors to protect a substantial portion of our proprietary rights. We may have limited, if any, control or involvement over the defense of these claims, and our licensors could be subject to injunctions and temporary or permanent exclusionary orders in the U.S. or other countries.

We or our licensors may also be notified of alleged infringement and be sued for infringement of third-party patents or other proprietary rights. Our licensors are not obligated to defend or assist in our defense against third-party claims of infringement. We have limited, if any, control over the amount or timing of resources, if any, that our licensors devote on our behalf or the priority they place on defense of such third-party claims of infringement. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we or our licensors may not be successful in defending claims of intellectual property infringement by third parties,

which could have a material adverse affect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Finances and Capital Requirements

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

We began generating revenues from the commercialization of OFIRMEV in January 2011. Prior to that time, we focused primarily on in-licensing and developing OFIRMEV and our former product candidate, omiganan pentahydrochloride, with the goal of supporting regulatory approval for these product candidates. We have incurred losses in each year since our inception in May 2004, including net losses of \$56.6 million, \$45.5 million and \$57.1 million for the years ended December 31, 2010, 2009 and 2008, respectively. As of December 31, 2010, we had an accumulated deficit of \$273.7 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. For example, our development expenses decreased in 2010 and 2009 due to the completion of our clinical development program for OFIRMEV, and the discontinuation of our development program for our omiganan pentahydrochloride product candidate. However, we incurred increased pre-commercialization expenses during 2010 and 2009 as we prepared for the potential market launch of OFIRMEV, and we expect to incur significant sales, marketing and outsourced manufacturing expenses, as well as expenses related to the commercialization and marketing of this product. As a result, we expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

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

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

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

We have incurred and anticipate continuing to incur significant costs associated with our efforts to commercialize, market and sell OFIRMEV. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

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

We were incorporated in May 2004 and have only been conducting operations with respect to OFIRMEV since March 2006 and our discontinued omiganan pentahydrochloride product candidate since July 2004. Our initial operations were limited to organizing and staffing our company, in-licensing and conducting product development activities, including clinical trials and manufacturing development activities, for OFIRMEV and omiganan pentahydrochloride. Further, in 2009 we began to establish our commercial infrastructure for OFIRMEV, and in January 2011 we launched OFIRMEV and began generating revenues. We have not yet demonstrated an ability to successfully market and sell OFIRMEV or any other product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully commercializing pharmaceutical products.

Our quarterly operating results may fluctuate significantly.

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

- our ability to successfully market and sell OFIRMEV;
- our capacity to manage our commercial infrastructure and related expenses, including our recently hired sales and marketing personnel and our agreements with third parties for warehousing, distribution, cash collection and related commercial activities;
- our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our development programs for any future product candidates;
- any product liability or intellectual property infringement lawsuits in which we may become involved;
- regulatory developments affecting OFIRMEV or the product candidates of our competitors; and
- the level of underlying hospital demand for OFIRMEV and wholesalers' buying patterns.

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

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

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. For example, we undertook a public offering of our common stock in November 2010 through which we issued a total of 12.5 million shares and raised net proceeds of \$93.6 million. If we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. For example, in June 2010, we entered into an amended and restated loan and security agreement with Oxford Finance Corporation, Silicon Valley Bank and GE Business Financial Services Inc. for a credit facility of up to \$30.0 million. We drew the first advance of \$20.0 million under this loan in June 2010. We amended this facility and drew the second advance of \$10.0 million in November 2010, following FDA approval of OFIRMEV.

Our current loan and security agreement contains a variety of affirmative and negative covenants, including required financial reporting, limitations on the disposition of assets other than in the ordinary course of business, limitations on the incurrence of additional debt and other requirements. To secure our performance of our obligations under our 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, on July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access, and the SEC has since issued final rules implementing “say on pay” measures. Our efforts to comply with corporate governance and related requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management’s time from other business activities.

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

Our net operating loss carryforwards and research and development tax credits may expire and not be used. As of December 31, 2010, we have generated federal and state net operating loss carryforwards of approximately \$219.3 million and \$224.7 million, respectively. We also have federal and state research and development tax credit carryforwards of approximately \$4.2 million and \$2.2 million, respectively. Our net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2018 for state purposes if we have not used them prior to that time. Our federal tax credits will begin expiring in 2024 unless previously used and our state tax credits carryforward indefinitely. Additionally, under Internal Revenue Code Sections 382 and 383, the annual use of our net operating loss carryforwards and research tax credits will be limited in the event a cumulative change in our ownership occurs within a three-year period. We have not completed an analysis as to whether such a change of ownership has occurred, but in such an event, we may be limited to the amount of net operating loss carryforwards and research tax credits that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. In addition, California and certain states have suspended use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact on our operating results and financial condition.

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

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a difficult residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and continued unemployment concerns, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may 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 from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. For example, the volatility in the overall capital markets reached unprecedented levels during 2008 through 2010, which affected most equity securities. Similar market volatility could reduce the market price of our common stock in spite of our operating performance. Further, high stock price volatility could result in higher stock-based compensation expense.

The trading prices for our common stock during the 52 weeks ending December 31, 2010 ranged from a high of \$10.91 to a low of \$6.29. The market price of our common stock is likely to continue to be highly volatile and may fluctuate substantially due to many factors, including:

- announcements concerning our operating results and the hospital formulary acceptance of OFIRMEV;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of OFIRMEV to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- the filing of any ANDAs relating to OFIRMEV and any challenges to our patents and other intellectual property rights;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

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

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

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

For example, we undertook a public offering of our common stock in November 2010 through which we issued a total of 12.5 million shares, and in May 2009, we completed the registration of approximately 18.1 million shares of our common stock in connection with a financing transaction completed in February 2009. As a result, all of the shares currently outstanding may generally be freely sold in the public market, subject to volume and other limitations applicable to our affiliates. We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws.

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, 2010, our executive officers and directors and their affiliates together controlled approximately 40.4% 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. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors, including to delay or impede a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

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

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

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

Item 1B: *Unresolved Staff Comments*

Not applicable.

Item 2. *Properties*

We lease approximately 23,494 square feet of space in our headquarters in San Diego, California under a sublease that expires in 2012. We have no laboratory, research or manufacturing facilities; however we do own manufacturing equipment located at a third-party contractor. We currently do not plan to purchase or lease facilities for manufacturing, packaging or warehousing as such services are provided to us by third-party

contractors. We believe that our current facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. *Legal Proceedings*

Although we are involved in legal proceedings arising in the ordinary course of business, we are not currently engaged in any legal proceedings, nor is any legal proceeding threatened against us, that we believe would have a material adverse effect on our financial position, results of operations or liquidity.

Item 4. *(Removed and Reserved)*

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 28, 2011, there were 63,148,298 shares of common stock outstanding held by approximately 30 stockholders of record. Many stockholders hold their shares in street name. We believe that there are more than 4,000 beneficial owners of our common stock. The closing price of our common stock on the NASDAQ Global Market on December 31, 2010 was \$7.55 per share. The following table sets forth the high and low sales prices for our common stock as reported on the NASDAQ Global Market for the periods indicated:

| | Year Ended December 31, | | | |
|----------------------|-------------------------|--------|---------|--------|
| | 2010 | | 2009 | |
| | High | Low | High | Low |
| Period: | | | | |
| First Quarter | \$10.91 | \$8.41 | \$ 9.69 | \$5.68 |
| Second Quarter | \$10.63 | \$6.29 | \$11.52 | \$8.25 |
| Third Quarter | \$ 8.60 | \$6.59 | \$12.68 | \$9.37 |
| Fourth Quarter | \$10.00 | \$7.13 | \$11.76 | \$8.40 |

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2010, about our common stock that may be issued upon the exercise of stock options and the vesting of restricted stock units granted to employees, consultants and members of our board of directors under all existing equity compensation plans, including our 2006 Equity Incentive Award Plan and our 2004 Equity Incentive Award Plan. The 2006 Equity Incentive Award Plan was adopted at the time of our initial public offering in October 2006, which coincided with the discontinuance of the 2004 Equity Incentive Award Plan. We amended and restated this plan in April 2010, which became effective in May 2010 upon the approval by our stockholders. See Note 10 to the Notes to Financial Statements in Item 8 of this Annual Report on Form 10-K for further discussion of our equity plans.

Equity Compensation Plan Information

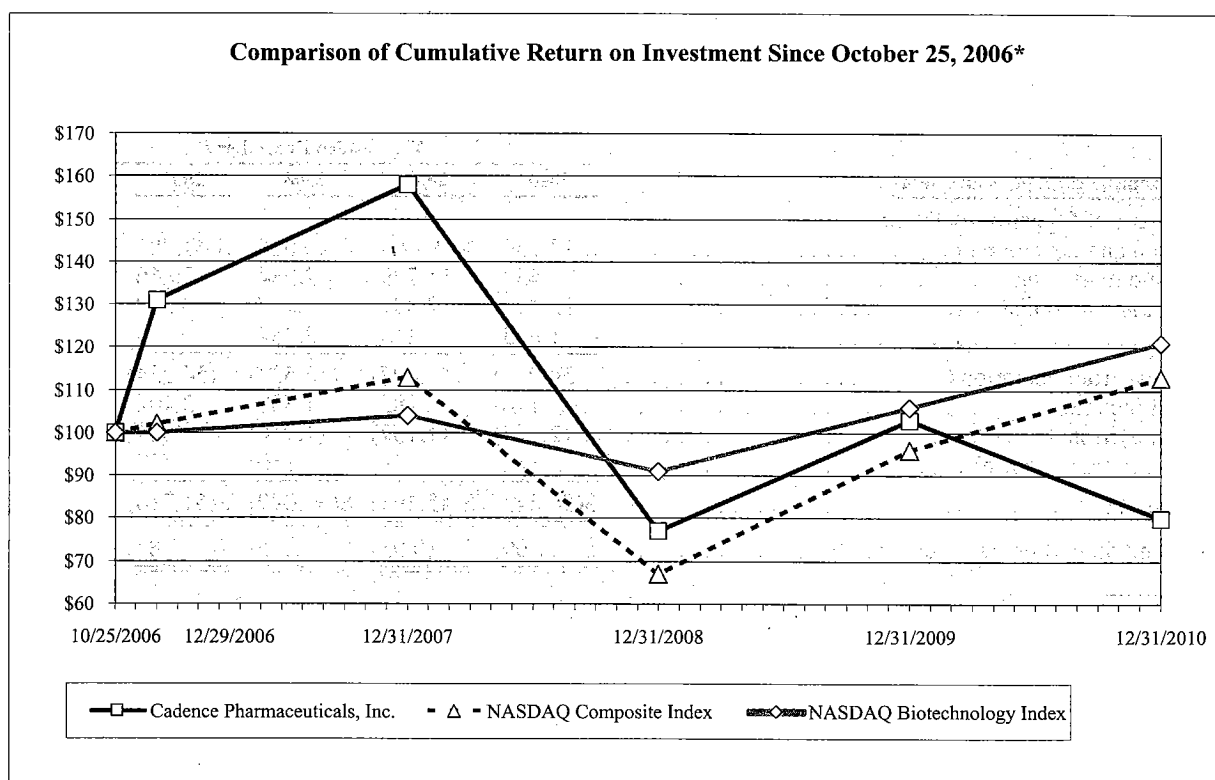
| | Number of securities to be issued upon exercise of outstanding options, restricted stock units, warrants and rights | Weighted average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|--|---|--|---|
| | (a) | (b) | (c) |
| Plan Category: | | | |
| Equity compensation plans approved by security holders | 7,135,315 ⁽¹⁾ | \$7.84 ⁽²⁾ | 563,584 ⁽³⁾ |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | <u>7,135,315</u> | <u>\$7.84⁽²⁾</u> | <u>563,564⁽³⁾</u> |

(1) Of these shares of common stock, 5,600,568 shares were subject to outstanding options under the 2006 Equity Incentive Award Plan and 1,399,089 shares were subject to outstanding options under the 2004 Equity Incentive Award Plan. In addition, 135,658 of the shares were subject to outstanding restricted stock units under the 2006 Equity Incentive Award Plan.

- (2) As restricted stock units do not have an exercise price, the weighted average exercise price does not take into account the 135,658 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 (i) 4% of our outstanding common stock on the applicable January 1 or (ii) such lesser amount determined by our board of directors. At January 1, 2010, 2009 and 2008, the board of directors approved the amount of shares authorized for future issuance under the 2006 Plan to be increased by 1,766,960 shares, 1,269,576 shares and 1,018,939 shares, respectively, under this provision.

Performance Graph

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



| | <u>10/25/2006</u> | <u>12/29/2006</u> | <u>12/31/2007</u> | <u>12/31/2008</u> | <u>12/31/2009</u> | <u>12/31/2010</u> |
|------------------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Cadence Pharmaceuticals, Inc. | \$100 | \$131 | \$158 | \$77 | \$103 | \$80 |
| NASDAQ Composite Index | \$100 | \$102 | \$113 | \$67 | \$96 | \$113 |
| NASDAQ Biotechnology Index | \$100 | \$100 | \$104 | \$91 | \$106 | \$121 |

* 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 Corporation, Silicon Valley Bank and GE Business Financial Services Inc. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

Issuer Repurchases of Equity Securities

Not applicable.

Item 6. Selected Financial Data

The selected financial data set forth below is derived from our audited financial statements and may not be indicative of future operating results. Audited balance sheets at December 31, 2010 and 2009 and the related audited statements of operations and of cash flows for each of the three years in the period ended December 31, 2010 and notes thereto appear elsewhere in this Annual Report on Form 10-K. Audited balance sheets at December 31, 2008, 2007 and 2006 and the related audited statements of operations and of cash flows for 2007 and 2006 are not included elsewhere in this Annual Report on Form 10-K.

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

| (in thousands, except per share data) | Year Ended December 31, | | | | |
|---|-------------------------|-------------------|-------------------|-------------------|-------------------|
| | 2010 | 2009 | 2008 | 2007 | 2006 |
| Statement of Operations Data: | | | | | |
| Research and development | \$ 13,757 | \$ 19,464 | \$ 40,018 | \$ 41,781 | \$ 47,827 |
| Sales and marketing | 26,455 | 11,729 | 2,984 | 2,866 | 810 |
| General and administrative | 12,892 | 12,891 | 11,147 | 9,587 | 4,946 |
| Other | 1,813 | 413 | 2,384 | — | — |
| Loss from operations | (54,917) | (44,497) | (56,533) | (54,234) | (53,583) |
| Interest income | 106 | 182 | 1,530 | 3,404 | 1,945 |
| Interest expense | (2,144) | (1,137) | (1,916) | (867) | (498) |
| Other income (expense) | 312 | (39) | (180) | (17) | (37) |
| Net loss | <u>\$(56,643)</u> | <u>\$(45,491)</u> | <u>\$(57,099)</u> | <u>\$(51,714)</u> | <u>\$(52,173)</u> |
| Basic and diluted net loss per share ⁽¹⁾ | <u>\$ (1.09)</u> | <u>\$ (0.93)</u> | <u>\$ (1.55)</u> | <u>\$ (1.81)</u> | <u>\$ (10.07)</u> |

(1) As a result of the issuance of 6,900 shares of common stock in our initial public offering in the fourth quarter of 2006 and the conversion of our preferred stock into 19,908 shares of common stock upon completion of our initial public offering, the issuance of 9,240 shares of common stock pursuant to an effective shelf registration in the first quarter of 2008, the issuance of 12,040 shares of common stock pursuant to a private placement in the first quarter of 2009 and the issuance of 12,500 shares of common stock pursuant to a public offering of common stock in the fourth quarter of 2010, there is a lack of comparability in the per share amounts between the periods presented. Please see Note 2 to the Notes to Financial Statements in Item 8 of this Annual Report on Form 10-K for further discussion.

| (in thousands) | As of December 31, | | | | |
|---|--------------------|-----------|-----------|-----------|-----------|
| | 2010 | 2009 | 2008 | 2007 | 2006 |
| Balance Sheet Data: | | | | | |
| Cash, cash equivalents and marketable securities | \$ 134,141 | \$ 82,006 | \$ 47,627 | \$ 55,393 | \$ 86,826 |
| Inventory | 485 | — | — | — | — |
| Working capital | 121,319 | 67,193 | 28,385 | 36,839 | 76,203 |
| Total assets | 163,786 | 92,563 | 55,148 | 64,612 | 93,092 |
| Long-term debt, less current portion and discount | 24,654 | — | 6,098 | 13,412 | 4,433 |
| Deficit accumulated during the development stage | (273,662) | (217,019) | (171,528) | (114,429) | (62,716) |
| Total stockholders' equity | 123,960 | 75,063 | 26,440 | 28,458 | 75,409 |

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 in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. We intend to build a leading franchise in the hospital setting, continuing to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations. In 2006, we in-licensed rights to OFIRMEV™ (acetaminophen) injection, which was approved by the U.S. Food and Drug Administration, or FDA, in November 2010 and commercially launched in the U.S. in January 2011. We intend to build a leading franchise in the hospital setting, continuing to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations.

Background

We were incorporated in May 2004 and during that year we focused on hiring our management team and initial operating employees, but substantial operations did not commence until September 2004.

OFIRMEV™

In March 2006, we in-licensed the exclusive U.S. and Canadian rights to OFIRMEV, a proprietary intravenous formulation of acetaminophen, from Bristol-Myers Squibb Company, or BMS, which currently markets the product in Europe and several other markets under the brand name *Perfalgan*®. In October 2006, we initiated our Phase III clinical development program for OFIRMEV and in May 2009, we submitted a new drug application, or NDA, to the FDA, requesting marketing approval of the product. On November 2, 2010, the FDA approved 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 2 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 sales force of 147 sales representatives that is supported by 13 field-based medical science liaisons and an experienced commercial management, marketing and sales operations team. The primary target audience for OFIRMEV will include anesthesiologists and surgeons. Other targets will include certified registered nurse anesthetists, emergency medicine physicians, intensivists, internists, obstetricians and other physicians throughout the hospital. Our commercial sales force will focus on reaching the top 1,800 to 1,900 U.S. hospitals, which we believe represent approximately 80% of the market opportunity for OFIRMEV. During 2011, our hospital sales specialists will be focused on the formulary adoption process at our target hospitals, which we believe is an important initial step for broad market acceptance.

We have established third-party manufacturing relationships for the production of OFIRMEV with Baxter Healthcare Corporation, or Baxter, and Lawrence Laboratories, an indirectly wholly-owned subsidiary of BMS. Under these agreements, we purchase the finished product at specified prices, subject to annual adjustments. We have a dedicated manufacturing line at Baxter and have entered into an agreement to fund a second production line at Baxter's facility to help us meet anticipated future demand. Additionally, we have entered into distribution and wholesaler agreements to support the inventory management and distribution of OFIRMEV.

Omiganan pentahydrochloride

In 2005, we initiated Phase III clinical trials for omiganan pentahydrochloride 1% aqueous gel, a topical antimicrobial. In March 2009, we announced that our Phase III clinical trial of this product candidate did not meet its primary endpoint. We discontinued our development efforts and terminated our license for this product candidate. At the same time, we implemented cost reduction measures and restructured our operations to make additional resources available for our OFIRMEV development program and other operating activities.

Option Agreement with Incline Therapeutics, Inc.

In June 2010 we entered into an agreement with Incline that provides us with the exclusive, irrevocable option to acquire Incline within a specified future time period. Incline is developing IONSYS™ (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery. We believe that IONSYS, if approved by the FDA, could represent a potentially significant commercial opportunity and be an excellent strategic fit with OFIRMEV. Our initial option period to acquire Incline extends until one day prior to Incline receiving the second tranche of its Series A financing, or June 2011, whichever occurs later. During this period, we may acquire Incline for an amount not to exceed \$135.0 million. During the following option period, the acquisition cost would be an amount not to exceed \$228.0 million, plus payment of an additional amount not to exceed \$57.0 million upon FDA approval of IONSYS.

We have incurred significant net losses since our inception and have financed our operations primarily through the issuance of equity securities in both public and private offerings. Most recently, we sold 12.5 million shares in a public offering in the fourth quarter of 2010 and received aggregate net proceeds of approximately \$93.6 million (after underwriting discounts and offering costs). From inception through December 31, 2010, we have received net proceeds of approximately \$364.9 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Additionally, we have entered into loan and security agreements with Oxford Finance Corporation, Silicon Valley Bank and GE Business Financial Services Inc. to provide us with growth capital. As of December 31, 2010 the principal balance outstanding on our current facility with this loan syndicate was \$30.0 million.

Revenues

As of December 31, 2010, we had not generated any revenues. However, in January 2011 we initiated commercial sales of OFIRMEV and began to generate revenue on sales of this product. We sell OFIRMEV to wholesalers and directly to hospitals. Our distribution channel includes our sales representatives, our third party logistics distributor and independent wholesalers who distribute the product directly to hospitals and other end-user customers. The majority of our shipments are made to wholesalers, with whom we have contracted to distribute the product. We have also contracted with group purchasing organizations to increase awareness of, and reduce market barriers for, OFIRMEV.

Until we have sufficient sales history, we intend to defer the recognition of revenue on sales to our wholesalers until the product is sold to hospitals and other end-user customers.

Cost of Sales

Our cost of sales consists primarily of our third-party manufacturing costs, third-party inventory management and distribution costs, internal manufacturing overhead, indirect and personnel overhead costs, freight, reserves for excess or obsolete inventory, and cost of purchasing the active pharmaceutical ingredient for OFIRMEV, acetaminophen. As of December 31, 2010, we had not generated any revenue and therefore had not incurred any cost of sales.

Royalty Expense

Royalty expense consists of the royalties we are required to pay BMS on the net sales of OFIRMEV. Additionally, the expense includes the amortization of the \$15.0 million license payment made to BMS and Pharmatop following the FDA approval of OFIRMEV, which we are amortizing based upon product sales. Further, the expense may include the amortization of anticipated milestone payments that may become due under the license agreement.

Research and Development Expenses

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.

Our historical research and development expenses relate predominantly to OFIRMEV and our discontinued omiganan pentahydrochloride product candidate. 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 we have capitalized non-investigational costs incurred since that time to inventory and capital, as appropriate. We expect to continue to incur research and development expenses related to OFIRMEV, however, it is difficult to anticipate the scope and magnitude of our future research and development expenses. For example, the FDA has required that we complete a post-approval clinical trial for OFIRMEV in pediatric patients under two years of age, and we may also conduct clinical studies to expand the indications for OFIRMEV. Moreover, any product candidates we may in-license or acquire in the future would likely require significant research and development resources. Therefore, we are unable to estimate with any certainty the costs we will incur in completing our development efforts for OFIRMEV or any other product candidate we might acquire or in-license.

A substantial portion of our external research and development costs are tracked on a project basis. However, our internal research and development resources are used in several projects and may not be attributable to a specific product candidate. For example, a substantial portion of our internal costs, including personnel and facility related costs, is not tracked on a project basis. We have summarized these costs in the following table. Costs that are not attributable to a specific product candidate, including salaries and related personnel costs, are included in the "other supporting costs" category (in thousands):

| | Year Ended December 31, | | | Period from |
|---|-------------------------|-----------------|-----------------|---|
| | 2010 | 2009 | 2008 | May 26, 2004 (Inception) through December 31, 2010 |
| OFIRMEV ⁽¹⁾⁽²⁾ | \$ 3,399 | \$ 7,014 | \$15,234 | \$ 67,806 |
| Omiganan pentahydrochloride ⁽³⁾⁽⁴⁾ | 5 | 1,663 | 14,809 | 57,464 |
| Other supporting costs | 10,353 | 10,787 | 9,975 | 45,587 |
| | <u>\$13,757</u> | <u>\$19,464</u> | <u>\$40,018</u> | <u>\$170,857</u> |

(1) We paid an up-front license fee of \$25.0 million in 2006 for OFIRMEV, which is included in the amount for the period from May 26, 2004 (inception) through December 31, 2010. As a result of the FDA's approval of the OFIRMEV NDA, we made a payment of \$15.0 million in the fourth quarter of 2010 pursuant to the

terms of the license agreement with BMS. We have capitalized the \$15.0 million payment on our balance sheet and intend to amortize the value based upon product sales. 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, in addition to royalties on the sales of OFIRMEV. These subsequent payments will be recognized as royalty expense, as appropriate, and will not be included in this table.

- (2) During 2010, we recorded a charge of \$1.5 million related to the partial cancellation of an equipment order resulting from the modification in the design of our planned second production line for OFIRMEV. This charge is presented separately in our statement of operations in "Other" operating expenses for the year ended December 31, 2010 and is not included in this table.
- (3) We paid an up-front license fee of \$2.0 million in 2004 for omiganan pentahydrochloride, of which \$1.5 million is included in the costs for the period from May 26, 2004 (inception) through December 31, 2010. As a result of the termination of our collaboration and license agreement with Migenix, Inc. in 2009, we will not be obligated to make any future milestone or royalty payments with respect to this product candidate.
- (4) During the fourth quarter of 2008, we recorded an impairment charge of \$2.4 million on our omiganan pentahydrochloride manufacturing equipment due to the discontinuance of our omiganan pentahydrochloride program. During 2009, we recorded adjustments to this impairment charge, reducing the charge by \$0.2 million as actual costs incurred in disposing of the assets were less than anticipated. Further, in 2009 we recorded a restructuring charge of \$0.6 million related to the discontinuation of the omiganan pentahydrochloride development program. These charges are presented separately on our statement of operations in "Other" operating expenses and is not included in this table.

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of salaries and related employee benefits for our sales and marketing team, marketing, advertising and promotional costs for OFIRMEV, selling expenses for our sales representatives, including travel-related and commercial infrastructure costs, and other costs related to our commercial organization, including facilities and overhead costs. In 2009, we began to focus significant resources on establishing our commercial organization and spent most of 2010 preparing for the commercial launch of OFIRMEV. Following approval of OFIRMEV in November 2010, we began the process of hiring and training our sales force and related personnel, and, by January 2011, we completed the hiring of 147 sales representatives.

We anticipate our sales and marketing expenses will continue to increase in the coming years as we execute our marketing and sales strategies for OFIRMEV. We will do this primarily through our dedicated, hospital-focused sales force, who will focus on the top 1,800 to 1,900 U.S. hospitals, which we believe represent approximately 80% of the market opportunity for OFIRMEV. We will also have implemented a variety of marketing programs to educate customers, including direct-to-physician promotional materials, peer-to-peer promotional programs, medical journal advertising, and participation in targeted medical conventions.

General and Administrative Expenses

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

Other Income and Expense

Our interest income consists primarily of interest earned on our cash, cash equivalents and short-term investments. Interest expense consists of the interest we have incurred under our loan and security agreements and the amortization of debt issuance costs. Other income and expense includes charges we have incurred to

recognize other-than-temporary declines in the market value of our available-for-sale securities, tax credits we have received, gains or losses recognized on transactions denominated in foreign currencies and other transactions not related to our operations.

Income Taxes

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

As of December 31, 2010, we had federal and state net operating loss carryforwards of approximately \$219.3 million and \$224.7 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2018 for state purposes. Additionally, we had both federal and state research and development tax credit carryforwards of approximately \$4.2 million and \$2.2 million, respectively. The federal tax credits will begin expiring in 2024 unless previously utilized and the state tax credits carryforward indefinitely. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards and development tax credit carryforwards that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating losses and tax credits before they expire. We have not completed a Section 382/383 study at this time to determine the impact ownership changes have had on our carryforwards. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recognized any federal or state income tax benefit in our statement of operations.

Critical Accounting Policies and Estimates

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

Our most critical accounting estimates include the valuation of our inventory, which impacts gross margin, our recognition of research and development expenses, which impacts operating expenses and accrued liabilities; stock-based compensation which impacts operating expenses; and the assessment of recoverability of long-lived assets, which primarily impacts operating expenses when we impair assets or accelerate depreciation. We also have other policies that we consider to be key accounting policies, such as our policies for deferred income tax assets and liabilities and our reserves for commitments and contingencies; however, these policies either do not meet the definition of critical accounting estimates described above or are related to items that are not currently material to our financial statements. Additionally, as we had not commenced sales of OFIRMEV at December 31, 2010, revenue recognition was not considered a critical accounting policy through that period; however, it will become a key accounting policy in subsequent periods as we recognize revenue on the sales of OFIRMEV.

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.

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 reserving them, analyzing forecasted demand versus quantities on hand and reserving for the excess, and identifying other specific reserves.

Research and Development Expenses

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

Stock-Based Compensation

We account for stock-based compensation by calculating the fair value of the award on the date of grant and recognize the expense over the applicable vesting period. We calculate the fair value of stock options using the Black-Scholes pricing model, which requires a number of estimates, including the expected lives of awards, interest rates, stock volatility and other assumptions. Restricted stock units, or RSUs, are measured based on the fair market values of the underlying stock on the 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.

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

| | <u>Year Ended December 31,</u> | | | <u>Period from</u> |
|---|--------------------------------|----------------|----------------|---|
| | <u>2010</u> | <u>2009</u> | <u>2008</u> | <u>May 26, 2004</u> <u>(Inception) through</u> <u>December 31,</u> <u>2010</u> |
| Research and development | \$ 3,058 | \$2,577 | \$1,967 | \$ 9,407 |
| Sales and marketing | 2,964 | 502 | 61 | 3,561 |
| General and administrative | 4,491 | 4,676 | 3,910 | 17,714 |
| Stock-based compensation expense included in operating expenses | <u>10,513</u> | <u>7,755</u> | <u>5,938</u> | <u>30,682</u> |
| Total stock-based compensation expense included in loss from operations | <u>\$10,513</u> | <u>\$7,755</u> | <u>\$5,938</u> | <u>\$30,682</u> |

Long-Lived Assets

A substantial portion of our capital assets are associated with our manufacturing equipment at our third-party manufacturer. In building these assets and creating additional capacity, we enter into agreements whereby we fund specified improvements to the facilities and the construction of the manufacturing equipment to be used

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

As the result of the discontinuation of our omiganan pentahydrochloride program, we recorded an impairment charge of \$2.4 million on our omiganan pentahydrochloride manufacturing equipment during the fourth quarter of 2008. In 2009, we recorded adjustments to this impairment charge, reducing it by \$0.2 million as actual costs incurred in disposing of the assets were less than anticipated. Additionally, during the second quarter of 2010, we modified the design of our planned second production line for our OFIRMEV product candidate resulting in the partial cancellation of a capital equipment order for which we have identified an alternative supplier. As a result of the partial cancellation of the equipment, we incurred a charge of \$1.5 million in 2010 to impair the costs accumulated in construction-in-process for the equipment and accrue for related termination charges.

Results of Operations

Years ended December 31, 2010 and 2009

Operating Expenses

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

Sales and Marketing Expenses. For the year ended December 31, 2010, our sales and marketing expenses increased \$14.8 million to \$26.5 million, compared to \$11.7 million for 2009. This increase was related to our efforts to establish our commercial infrastructure and prepare for the commercial launch of OFIRMEV. As part of these efforts, we increased our sales and marketing staff from two at the beginning of 2009 to approximately 200 at December 31, 2010. This increase in personnel significantly increased our salaries and related personnel costs in 2010 by \$11.5 million as compared to 2009, including an additional \$2.4 million of stock-based compensation charges. Moreover, we incurred additional consulting and other services related to the establishment and operating costs of our commercial infrastructure in 2010.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2010 remained constant with the comparable 2009 period, at \$12.9 million. While we incurred

additional costs related to improving our technology infrastructure and other costs related to preparing for the launch of OFIRMEV, these increases were mostly offset by cost reductions in our business development and investor relations functions.

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

Other Income and Expenses, Net

Net other expense increased \$0.7 million for the year ended December 31, 2010, to \$1.7 million, compared to \$1.0 million in 2009. This increase was primarily due to the additional interest expense incurred from our \$20.0 million drawdown on our \$30.0 million loan and security agreement in June 2010 at a fixed interest rate of 11.33%. In November 2010, we drew the remaining \$10.0 million from this loan facility at a fixed interest rate of 10.08%. The \$30.0 million facility, established in June 2010, amended and replaced a \$15.0 million facility that had fixed interest rates of 7.83% and 7.74% on drawdowns of \$5.0 million and \$10.0 million, respectively. Partially offsetting the increase in interest expense was the receipt of \$0.2 million in federal government grants from the Qualifying Therapeutic Discovery Project program under section 48D of the Internal Revenue Code.

Years ended December 31, 2009 and 2008

Operating Expenses

Research and Development Expenses. Research and development expenses decreased \$20.5 million for the year ended December 31, 2009 to \$19.5 million, as compared to \$40.0 million in 2008. This reduction was primarily due to a \$13.1 million decrease in spending due to the discontinuation of our omiganan pentahydrochloride product candidate. Additionally, research and development spending on OFIRMEV decreased \$8.2 million in 2009 as compared to 2008, as we completed the clinical development program and filed an NDA with the FDA in May 2009.

Partially offsetting these decreases was an increase in the supporting costs for these programs, including research and development personnel and facility-related costs. More specifically, as compared to 2008, these other supporting costs increased \$0.8 million in 2009 to \$10.8 million, which was primarily related to additional salary and related personnel costs, including an additional \$0.6 million in stock-based compensation charges from additional equity awards outstanding during the 2009 period as compared to the same period in 2008.

Sales and Marketing Expenses. Marketing expenses increased \$8.7 million for the year ended December 31, 2009, to \$11.7 million, compared to \$3.0 million in 2008. This increase was primarily due to the development of our commercial and supply operations functions in during 2009, as we began to establish our commercial infrastructure in anticipation of the launch of OFIRMEV. As part of our development efforts, we increased our sales and marketing staff from two at the end of 2008 to 40 at the end of 2009. Moreover, we incurred additional advertising and promotion costs, outside service fees and market research costs and supported additional grants and continuing medical education in 2009 as compared to 2008.

General and Administrative Expenses. General and administrative expenses increased \$1.8 million for the year ended December 31, 2009 to \$12.9 million, compared to \$11.1 million in 2008. This increase was primarily due to increases in salaries and related personnel costs, including an additional \$0.8 million in stock-based

compensation charges from additional equity awards outstanding in 2009 as compared to 2008. Additionally, we incurred additional legal expenses and costs to enhance our information technology infrastructure in 2009 as compared to 2008 as we prepared for the commercialization of OFIRMEV.

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

Other Income and Expenses, Net

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

Liquidity and Capital Resources

As a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates for use in the hospital setting, we enter into agreements to acquire the rights to develop and commercialize product candidates. For example, we obtained the exclusive patent rights and know-how for OFIRMEV, currently our only product, for the U.S. and Canada pursuant to our license agreement with BMS. Under this agreement, we paid to BMS a \$25.0 million up-front fee. We made an additional \$15.0 million payment in the fourth quarter of 2010 pursuant to the terms of the agreement 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. In addition, we are also obligated to pay royalties on any net sales of OFIRMEV. Moreover, in the second quarter of 2010 we entered into an option agreement pursuant to which we obtained an option to acquire Incline during two option periods. In consideration for the option we paid a \$3.5 million upfront option fee and will pay a second \$3.5 million fee upon Incline receiving the second tranche of its Series A financing if we have not yet exercised our option to acquire Incline. During the first option period, we may acquire Incline for an amount not to exceed \$135.0 million. During the second option period, we may acquire Incline for an amount not to exceed \$228.0 million, plus payment of an additional amount not to exceed \$57.0 million upon FDA approval of IONSYS. We had also previously entered into a license agreement for our former omiganan pentahydrochloride product candidate under which we paid to Migenix an aggregate of \$2.0 million in the form of an up-front fee, including the purchase of 617,284 shares of Migenix common stock. In May 2009, we terminated our license agreement with Migenix, and we will not be required to make future milestone or royalty payments under this agreement.

As of December 31, 2010, we had not yet commenced sales of OFIRMEV and had not realized any revenue. Further, we have incurred significant net losses since our inception and, as of December 31, 2010, we had accumulated a deficit of \$273.7 million. These losses have resulted principally from costs incurred in connection with research and development activities, including license fees, costs of clinical trial activities associated with our product candidates, the establishment of our commercial infrastructure, pre-commercialization manufacturing development activities and general and administrative expenses. We expect to continue to incur operating losses and expend significant resources in connection with our marketing and sales efforts for OFIRMEV, and related to

our efforts to increase our manufacturing capacity to meet anticipated demand for this product. Further, we could incur significant expense if we acquire or in-license additional products, technologies or businesses that are complementary to our own.

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

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

Since inception, our operations have been financed primarily through the issuance of equity securities, in both public and private offerings. From our inception through December 31, 2010, we have received net proceeds of approximately \$364.9 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Through December 31, 2010, the sales of shares of our preferred stock, common stock and warrants were as follows:

- from July 2004 to December 2010 (excluding our initial public offering, our February 2008 registered direct offering, our February 2009 private placement and our 2010 public offering), we issued and sold a total of 2,456,576 shares of common stock to our founders, employees, directors and consultants for aggregate net proceeds of \$1.0 million;
- from July 2004 to August 2004, we issued and sold a total of 8,085,108 shares of Series A-1 preferred stock for aggregate net proceeds of \$7.5 million;
- from June 2005 to September 2005, we issued and sold a total of 17,675,347 shares of Series A-2 preferred stock for aggregate net proceeds of \$17.6 million;
- in March 2006, we issued and sold a total of 53,870,000 shares of Series A-3 preferred stock for aggregate net proceeds of \$53.8 million;
- in the fourth quarter of 2006, we completed our initial public offering in which we issued and sold a total of 6,900,000 shares of our common stock for aggregate net proceeds of \$55.9 million;
- in February 2008, we completed a registered direct offering pursuant to an effective shelf registration in which we issued and sold a total of 9,240,307 shares of our common stock for aggregate net proceeds of \$49.1 million;
- in February 2009, we raised aggregate net proceeds of approximately \$86.2 million through a private placement transaction in which we issued 12,039,794 shares of common stock and warrants to purchase up to 6,019,897 additional shares of common stock at a price of \$7.84, all of which remain outstanding; and
- 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.

Additionally, in February 2006, we entered into a \$7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation to provide us with growth capital. We drew down \$7.0 million in

June 2006 and in July 2009 we made the final payment to retire the \$7.0 million obligation. In November 2007, we amended the \$7.0 million loan and security agreement and entered into the Second Amendment to Loan and Security Agreement with the same parties and GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services, Inc.), to secure an additional \$15.0 million loan facility. In December 2007, we drew down \$15.0 million under the Second Amendment and in June 2010, we replaced the \$15.0 million loan facility and secured a \$30.0 million loan facility. An advance of \$20.0 million was made in June 2010 on the new facility, a portion of which paid the outstanding balance of the \$15.0 million facility, and we drew the remaining \$10.0 million in November 2010. In connection with each loan agreement, we issued warrants to the lenders to purchase shares of our stock and as of December 31, 2010, 63,079 shares of common stock had been issued from the exercise of warrants. Warrants to purchase an additional 50,331 common shares at \$12.67 per share and 254,793 common shares at \$7.0645 per share remain outstanding from our loan agreements.

Liquidity

As of December 31, 2010, we had \$112.2 million in cash and cash equivalents, an increase of \$36.3 million from the \$75.9 million at December 31, 2009. This increase was primarily due to proceeds, net of offering costs and underwriting discounts and commissions, received from our public offering completed in December 2010 of approximately \$93.6 million and the proceeds we received from the draws on our \$30.0 million debt facility, net of fees and the payoff of our \$15.0 million facility, of \$23.2 million. Partially offsetting the increase from these proceeds was cash used in operations (\$58.9 million), net purchases of available-for-sale investment securities (\$16.0 million), purchases of property and equipment (\$3.8 million) and the upfront option fee paid to Incline (\$3.5 million).

The \$58.9 million of cash used in operations for 2010 represents a \$16.9 million increase from the \$42.0 million of cash used in operations during 2009. This increase in our use of cash during 2010 was primarily due to the \$15.0 million license payment made to BMS pursuant to the terms of the contract as a result of the FDA approval of our OFIRMEV NDA. Additionally, our operating loss in 2010, adjusted for non-cash expenses, increased \$6.4 million as compared to 2009. Partially offsetting this increase in the use of cash was an increase in our accounts payable and accrued liabilities as of December 31, 2010 as compared to December 31, 2009 due to increased expense activity in the fourth quarter of 2010 as compared to 2009 as we prepared for the launch of OFIRMEV.

Following approval of our NDA in November 2010, we began to produce commercial quantities of OFIRMEV and, as of December 31, 2010, we had produced \$0.4 million of inventory. We intend to continue to build our inventory balances in order to ensure we have a sufficient supply of finished product available.

Our property and equipment balance at December 31, 2010 increased \$0.7 million to \$9.0 million, from \$8.3 million as of December 31, 2009. This increase was primarily due to \$3.8 million in capital equipment purchases, primarily for the manufacture of OFIRMEV, partially offset by a \$1.5 million impairment we incurred from a modification in the design of our planned second production line and \$0.8 million of depreciation taken during the year. We are currently negotiating a development plan for a capacity increase at Baxter, our primary third-party manufacturer for OFIRMEV. As part of this plan, we will fund all capital equipment and facility improvements necessary for the capacity increase. However, we cannot reasonably estimate the cost of this expansion at this time, as the capacity increase development plan has not been completed.

Capital Resources

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

- the costs associated with our efforts to commercialize OFIRMEV;

- the costs to manufacture commercial quantities of OFIRMEV at acceptable cost levels;
- the market acceptance for OFIRMEV and level of sales we are able to generate for the product; and
- any determination to exercise our option to acquire Incline.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with our available financial resources, generated from the proceeds of offerings of our equity securities and our existing borrowings under our amended loan and security agreement. These financial resources may not be adequate to sustain our operations until we are able to generate significant positive cash from operations and we may be required to finance future cash needs through the sale of additional equity securities, strategic collaboration agreements and debt financing. However, we cannot be certain that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. The capital markets have experienced volatility in recent years and the availability of credit has been adversely affected by illiquid credit markets and wide credit spreads. Further, concern about the stability of the markets in general, and the strength of counterparties specifically, has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may adversely affect our ability to obtain additional financing on terms acceptable to us, or at all. If these market conditions continue, they may limit our ability to timely replace maturing liabilities and to access the capital markets to meet liquidity needs. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our programs or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. Additionally, if we raise funds by issuing equity securities, dilution to existing stockholders would result; and if we raise funds by incurring additional debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Other Significant Cash and Contractual Obligations

The following table summarizes our scheduled contractual obligations and commitments that will affect our future liquidity as of December 31, 2010 (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 | \$38,125 | \$ 7,646 | \$27,532 | \$2,947 | \$— |
| Third-party manufacturing obligations ⁽¹⁾ | 15,110 | 1,740 | 6,670 | 6,700 | — |
| Operating leases ⁽²⁾ | 2,153 | 1,219 | 934 | — | — |
| Capacity upgrades ⁽³⁾ | — | — | — | — | — |
| Other purchase obligations ⁽⁴⁾ | 4,055 | 3,474 | 581 | — | — |
| Incline transaction option payment ⁽⁵⁾ | — | — | — | — | — |
| License obligations ⁽⁶⁾ | — | — | — | — | — |
| Total ⁽⁷⁾ | <u>\$59,443</u> | <u>\$14,079</u> | <u>\$35,717</u> | <u>\$9,647</u> | <u>\$—</u> |

(1) We have contracted the commercial supply of OFIRMEV with third-party manufacturers. Under these agreements, we are required to purchase a certain minimum number of vials each year during the term of the contract. The amounts presented represent our estimates of the minimum required expenditures under these agreements.

(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) We are currently negotiating the development plan for an increase in manufacturing capacity at Baxter, our primary third-party manufacturer for OFIRMEV, whereby we will fund all facility improvements under the development plan. In addition, we are required to reimburse Baxter for all reasonable costs for de-installation of our equipment and the restoration of Baxter's manufacturing facility to its pre-installation condition. However, we are not able to reasonably estimate the cost and timing of these costs at this time and therefore have not included these obligations in the amounts presented.

- (4) Includes purchase commitments for capital expenditures related to our capacity increase at Baxter and other purchase obligations for services at fixed minimum costs.
- (5) Under our option agreement with Incline, we are required to make a \$3.5 million payment upon Incline receiving the second tranche of its Series A financing if we have not yet exercised our option to acquire Incline. If we exercise the option during the first option period, we may acquire Incline for an amount not to exceed \$135.0 million. If we exercise the option during the second option period, we may acquire Incline for an amount not to exceed \$228.0 million, plus payment of an additional amount not to exceed \$57.0 million upon FDA approval of IONSYS. Further, we may elect to extend the second option period for two additional three-month periods upon the payment of \$2.5 million to Incline for each period. We are unable to estimate with certainty the timing and potential of these payments as they are dependent upon certain events and circumstances which may or may not occur. Therefore, we have not included these obligations in the amounts presented.
- (6) Under our license agreement with BMS, we may be required to make additional future payments up to a total of \$25.0 million, due 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. License payments may be increased based on the timing of various milestones and the extent to which the licensed technologies are pursued for other indications. These milestone payments and royalty payments under our license agreements are not included in the table above because at this time we cannot determine when, or if, the related milestones will be achieved or the events triggering the commencement of payment obligations will occur.
- (7) We also enter into unconditional purchase obligations with various vendors and suppliers of goods and services in the normal course of operations through purchase orders or other documentation, or that are undocumented except for an invoice. Such unconditional purchase obligations are generally outstanding for periods less than a year and are settled by cash payments upon delivery of goods and services and are not reflected in this line item.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2010.

Recent Accounting Pronouncements

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

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

Cash Equivalents and Investments

Our cash equivalents and short-term investments are classified as available-for-sale. As of December 31, 2010 our holdings consisted of investments in money market funds, debt obligations of municipalities, commercial paper and certificates of deposit. These investments were made in accordance with an investment policy approved by our board of directors which specifies the categories, allocations, and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments that we invest in could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio which may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations would be materially impacted by an immediate change of 10% in interest rates.

We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash, cash equivalents and investment securities have significant risk of default or illiquidity. We made this determination based on discussions with our investment advisors and a review of our holdings. For example, our investments in money market funds have been placed with reputable financial institutions and the holdings of these were invested solely in U.S. government agency securities and U.S. treasuries where an actively traded market is observed and through which values are determined. While we believe our cash, cash equivalents and investment securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. All of our investments are held at fair value. The following table shows the fair value of our cash equivalents and investments as of December 31, 2010 (in thousands):

| | <u>Amortized Cost Basis</u> | <u>Fair Value</u> |
|--|---------------------------------|-------------------|
| Cash equivalents | \$112,111 | \$112,111 |
| Available-for-sale marketable securities | \$ 21,966 | \$ 21,966 |

Debt

The loans under our amended and restated loan and security agreement have fixed interest rates. Consequently, we do not have significant interest rate cash flow exposure on our debt. The aggregate balance of the loans, net of the loan discount, under the agreement at December 31, 2010 was \$28.7 million, and is collateralized by substantially all of our assets (excluding intellectual property). Under the terms of the agreement, we are precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and are subject to various non-financial covenants and prepayment penalties.

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Cadence Pharmaceuticals, Inc. as of December 31, 2010 and 2009, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010, and for the period from May 26, 2004 (Inception) through December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cadence Pharmaceuticals, Inc. at December 31, 2010 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, and for the period from May 26, 2004 (Inception) through December 31, 2010, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Cadence Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 4, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 4, 2011

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

BALANCE SHEETS
(in thousands, except share and per share data)

| | December 31, | |
|---|--------------|-----------|
| | 2010 | 2009 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 112,175 | \$ 75,859 |
| Investments in marketable securities | 21,966 | 6,147 |
| Restricted cash | 150 | 1,498 |
| Inventory | 485 | — |
| Prepaid expenses | 1,232 | 518 |
| Other current assets | 36 | 31 |
| Total current assets | 136,044 | 84,053 |
| Property and equipment, net | 8,986 | 8,300 |
| Intangible assets | 15,000 | — |
| Restricted cash | 190 | 190 |
| Other assets | 3,566 | 20 |
| Total assets | \$ 163,786 | \$ 92,563 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,416 | \$ 2,657 |
| Accrued liabilities | 7,286 | 7,761 |
| Current portion of long-term debt, less discount of \$429 and \$158, respectively ... | 4,023 | 6,442 |
| Total current liabilities | 14,725 | 16,860 |
| Long-term debt, less current portion and discount of \$894 and \$-, respectively | 24,654 | — |
| Other long-term liabilities | 447 | 640 |
| Total liabilities | 39,826 | 17,500 |
| 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, 2010 and 2009, respectively | — | — |
| Common stock, \$0.0001 par value; 100,000,000 shares authorized, 63,107,361 shares and 50,484,588 shares issued and outstanding at December 31, 2010 and 2009, respectively | 6 | 5 |
| Additional paid-in capital | 397,616 | 292,077 |
| Accumulated other comprehensive income | — | — |
| Deficit accumulated during the development stage | (273,662) | (217,019) |
| Total stockholders' equity | 123,960 | 75,063 |
| Total liabilities and stockholders' equity | \$ 163,786 | \$ 92,563 |

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF OPERATIONS
(in thousands, except per share data)

| | Year Ended December 31, | | | Period from May 26, 2004 (Inception) through December 31, 2010 |
|---|-------------------------|------------|------------|--|
| | 2010 | 2009 | 2008 | |
| Operating expenses: | | | | |
| Research and development | \$ 13,757 | \$ 19,464 | \$ 40,018 | \$ 170,857 |
| Sales and marketing | 26,455 | 11,729 | 2,984 | 45,125 |
| General and administrative | 12,892 | 12,891 | 11,147 | 53,751 |
| Other | 1,813 | 413 | 2,384 | 4,610 |
| Total operating expenses | 54,917 | 44,497 | 56,533 | 274,343 |
| Loss from operations | (54,917) | (44,497) | (56,533) | (274,343) |
| Other (expense) income: | | | | |
| Interest income | 106 | 182 | 1,530 | 7,432 |
| Interest expense | (2,144) | (1,137) | (1,916) | (6,563) |
| Other expense | 312 | (39) | (180) | (188) |
| Total other (expense) income, net | (1,726) | (994) | (566) | 681 |
| Loss before income tax | (56,643) | (45,491) | (57,099) | (273,662) |
| Net loss | \$(56,643) | \$(45,491) | \$(57,099) | \$(273,662) |
| Basic and diluted net loss per share ⁽¹⁾ | \$ (1.09) | \$ (0.93) | \$ (1.55) | |
| Shares used to compute basic and diluted net loss per share ⁽¹⁾ | 52,042 | 48,754 | 36,824 | |

⁽¹⁾ As a result of the issuance of 12,500 shares of common stock pursuant to a public offering in the fourth quarter of 2010, 12,040 shares of common stock pursuant to a private placement in the first quarter of 2009 and 9,240 shares of common stock pursuant to a public offering in the first quarter of 2008, there is a lack of comparability in the per share amounts between the periods presented. Please see Note 2 of the Notes to Financial Statements for further discussion.

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except per share data)

| | Series A-1 to A-3 Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income | Deficit Accumulated During the Development Stage | Total Stockholders' Equity | Comprehensive Loss |
|---|---|----------|---------------|----------|----------------------------------|---|--|----------------------------------|-----------------------|
| | Shares | Amount | Shares | Amount | | | | | |
| Issuance of common stock to founders in July at \$0.004 per share | — | \$— | 1,125 | \$— | \$ 5 | \$— | \$ — | \$ 5 | |
| Issuance of Series A-1 preferred stock, net of \$60 offering costs in July and August at \$0.94 per share | 8,085 | 1 | — | — | 7,539 | — | — | 7,540 | |
| Issuance of common stock from option exercises under equity compensation plans | — | — | 45 | — | 18 | — | — | 18 | |
| Issuance of common stock options for consulting services in November | — | — | — | — | 1 | — | — | 1 | |
| Net Loss | — | — | — | — | — | — | (2,837) | (2,837) | \$ (2,837) |
| Balance at December 31, 2004 | 8,085 | 1 | 1,170 | — | 7,563 | — | (2,837) | 4,727 | \$ (2,837) |
| Issuance of Series A-2 preferred stock, net of \$57 offering costs in June and September at \$1.00 per share | 17,675 | 2 | — | — | 17,616 | — | — | 17,618 | |
| Issuance of common stock from option exercises under equity compensation plans, net of repurchase of shares from option exercises | — | — | 734 | — | 106 | — | — | 106 | |
| Net Loss | — | — | — | — | — | — | (7,706) | (7,706) | \$ (7,706) |
| Balance at December 31, 2005 | 25,760 | 3 | 1,904 | — | 25,285 | — | (10,543) | 14,745 | \$ (7,706) |
| Issuance of Series A-3 preferred stock, net of \$95 offering costs in March at \$1.00 per share | 53,870 | 5 | — | — | 53,770 | — | — | 53,775 | |
| Conversion of preferred stock in connection with initial public offering in October | (79,630) | (8) | 19,908 | 2 | 6 | — | — | — | |
| Initial public offering of common stock, net of \$6,205 offering costs, in October at \$9.00 per share | — | — | 6,900 | 1 | 55,894 | — | — | 55,895 | |
| Issuance of warrants in February to purchase 385 shares of common stock at \$1.00 per share | — | — | — | — | 314 | — | — | 314 | |
| Cashless warrant exercise in November at \$9.45 per shares | — | — | 28 | — | — | — | — | — | |
| Issuance of common stock from option exercises under equity compensation plans | — | — | 353 | — | 466 | — | — | 466 | |
| Collection of stock subscription receivable | — | — | — | — | 188 | — | — | 188 | |
| Stock-based compensation | — | — | — | — | 2,135 | — | — | 2,135 | |
| Unrealized gain on investment securities | — | — | — | — | — | 64 | — | 64 | \$ 64 |
| Net Loss | — | — | — | — | — | — | (52,173) | (52,173) | (52,173) |
| Balance at December 31, 2006 | — | — | 29,093 | 3 | 138,058 | 64 | (62,716) | 75,409 | \$ (52,109) |

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY—Continued
(in thousands, except per share data)

| | Series A-1 to A-3 Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income | Deficit Accumulated During the Development Stage | Total Stockholders' Equity | Comprehensive Loss |
|--|---|------------|---------------|-------------|----------------------------------|---|--|----------------------------------|-----------------------|
| | Shares | Amount | Shares | Amount | | | | | |
| Issuance of warrants in November to purchase 50 shares of common stock at \$12.67 per share | — | — | — | — | 474 | — | — | 474 | |
| Cashless warrant exercise in March at \$15.04 per share | — | — | 35 | — | — | — | — | — | |
| Net repurchase of common stock from option repurchases under equity compensation plans | — | — | (15) | — | 8 | — | — | 8 | |
| Stock-based compensation | — | — | — | — | 4,340 | — | — | 4,340 | |
| Unrealized loss on investment securities | — | — | — | — | — | (59) | — | (59) | \$ (59) |
| Net Loss | — | — | — | — | — | — | (51,713) | (51,713) | (51,713) |
| Balance at December 31, 2007 | — | — | 29,113 | 3 | 142,880 | 5 | (114,429) | 28,459 | \$(51,772) |
| Registered direct offering of common stock, net of \$204 offering costs, in February at \$5.34 per share | — | — | 9,240 | 1 | 49,138 | — | — | 49,139 | |
| Issuance of common stock from option exercises under equity compensation plans | — | — | 11 | — | 9 | — | — | 9 | |
| Stock-based compensation | — | — | — | — | 5,938 | — | — | 5,938 | |
| Unrealized loss on investment securities | — | — | — | — | — | (5) | — | (5) | \$ (5) |
| Net Loss | — | — | — | — | — | — | (57,099) | (57,099) | (57,099) |
| Balance at December 31, 2008 | — | — | 38,364 | 4 | 197,965 | — | (171,528) | 26,441 | \$(57,104) |
| Private placement offering of common stock, net of \$353 offering costs, in February at \$7.13 per share and warrants to purchase 6,020 shares of common stock at \$7.84 per share for \$0.125 per warrant | — | — | 12,040 | 1 | 86,242 | — | — | 86,243 | |
| Issuance of common stock from option exercises under equity compensation plans | — | — | 81 | — | 115 | — | — | 115 | |
| Stock-based compensation | — | — | — | — | 7,755 | — | — | 7,755 | |
| Net Loss | — | — | — | — | — | — | (45,491) | (45,491) | \$(45,491) |
| Balance at December 31, 2009 | — | — | 50,485 | 5 | 292,077 | — | (217,019) | 75,063 | \$(45,491) |
| Issuance of warrants in June to purchase 255 shares of common stock at \$7.0645 per share | — | — | — | — | 1,237 | — | — | 1,237 | |
| Public offering of common stock, net of \$6,445 offering costs, in November and December at \$8.00 per share | — | — | 12,500 | 1 | 93,554 | — | — | 93,555 | |
| Issuance of common stock from option exercises and lapse of restricted stock units under equity compensation plans | — | — | 122 | — | 235 | — | — | 235 | |
| Stock-based compensation | — | — | — | — | 10,513 | — | — | 10,513 | |
| Net Loss | — | — | — | — | — | — | (56,643) | (56,643) | \$(56,643) |
| Balance at December 31, 2010 | — | \$— | 63,107 | \$ 6 | \$397,616 | \$— | \$(273,662) | \$123,960 | \$(56,643) |

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF CASH FLOWS
(in thousands)

| | Year Ended December 31, | | | Period from May 26, 2004 (Inception) through December 31, 2010 |
|---|-------------------------|------------------|------------------|--|
| | 2010 | 2009 | 2008 | |
| Operating activities | | | | |
| Net loss | \$(56,643) | \$(45,491) | \$(57,099) | \$(273,662) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation | 758 | 537 | 530 | 2,608 |
| Loss on disposal of assets | 55 | 7 | 31 | 130 |
| Impairment of long-lived assets | 1,522 | — | 2,353 | 3,875 |
| Adjustment to estimate of impairment of long-lived assets | — | (181) | — | (181) |
| Impairment of available-for-sale securities | — | 45 | 177 | 450 |
| Stock-based compensation | 10,513 | 7,755 | 5,938 | 30,682 |
| Non-cash interest expense | 32 | 26 | 31 | 105 |
| Amortization of discount on note payable | 373 | 219 | 264 | 1,047 |
| Accretion of premiums on available-for-sale securities, net of accretion of discounts | 29 | 130 | — | 159 |
| Changes in operating assets and liabilities: | | | | |
| Prepaid expenses and other current assets | (585) | (444) | 690 | (1,341) |
| Intangible assets | (15,000) | — | — | (15,000) |
| Inventories | (485) | — | — | (485) |
| Accounts payable | 653 | (1,930) | 3,017 | 3,444 |
| Accrued liabilities and other liabilities | (82) | (2,721) | (5,620) | 5,537 |
| Net cash used in operating activities | <u>(58,860)</u> | <u>(42,048)</u> | <u>(49,688)</u> | <u>(242,632)</u> |
| Investing activities | | | | |
| Purchases of marketable securities | (24,201) | (10,738) | — | (42,389) |
| Maturities of marketable securities | 8,250 | 4,575 | — | 19,825 |
| Investment in unconsolidated entity | (3,500) | — | — | (3,500) |
| Restricted cash | 1,348 | 1,046 | 134 | (340) |
| Purchases of property and equipment | (3,754) | (3,267) | (1,743) | (13,531) |
| Proceeds from the sale of property and equipment | 3 | — | — | 3 |
| Net cash used in investing activities | <u>(21,854)</u> | <u>(8,384)</u> | <u>(1,609)</u> | <u>(39,932)</u> |
| Financing activities | | | | |
| Proceeds from issuance of common stock | 93,790 | 86,358 | 49,148 | 286,278 |
| Disbursements from repurchase of common stock | — | — | — | (19) |
| Proceeds from sale of preferred stock, net | — | — | — | 78,934 |
| Borrowings under debt agreements, net of fees | 29,591 | — | — | 51,546 |
| Principal payments under debt agreements | (6,351) | (7,694) | (5,617) | (22,000) |
| Net cash provided by financing activities | <u>117,030</u> | <u>78,664</u> | <u>43,531</u> | <u>394,739</u> |
| Net increase (decrease) in cash and cash equivalents | 36,316 | 28,232 | (7,766) | 112,175 |
| Cash and cash equivalents at beginning of period | 75,859 | 47,627 | 55,393 | — |
| Cash and cash equivalents at end of period | <u>\$112,175</u> | <u>\$ 75,859</u> | <u>\$ 47,627</u> | <u>\$ 112,175</u> |
| Supplemental disclosures | | | | |
| Issuance of warrants in connection with loan and security agreement | \$ 1,237 | \$ — | \$ — | \$ 2,025 |
| Shares in unconsolidated entity acquired in option purchase agreement | \$ 500 | \$ — | \$ — | \$ 500 |
| Assets acquired through lease concessions | \$ — | \$ — | \$ — | \$ 1,191 |
| Property and equipment purchases in accounts payable and accrued expenses | \$ 371 | \$ 1,101 | \$ — | \$ 371 |
| Unrealized gain loss on investment securities | \$ — | \$ — | \$ (5) | \$ — |
| Cash paid for interest and fees | \$ 1,986 | \$ 814 | \$ 1,483 | \$ 5,316 |

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

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

1. The Company

Cadence Pharmaceuticals, Inc. (the "Company") was incorporated in the state of Delaware in May 2004. The Company is a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. The Company's primary activities since incorporation have been conducting research and development activities, including clinical trials, of the product candidates in its portfolio; organizational activities, including recruiting personnel and establishing office facilities; establishing its commercial manufacturing and sales infrastructure; and raising capital to fund these activities.

In March 2006, the Company in-licensed the exclusive U.S. and Canadian rights to OFIRMEV™, an intravenous formulation of acetaminophen, from Bristol-Myers Squibb Company ("BMS"). In May 2009, the Company submitted a New Drug Application ("NDA") for OFIRMEV to the Food and Drug Administration ("FDA") and on February 10, 2010, received a complete response letter from the FDA, which stated the NDA could not be approved due to deficiencies observed during the FDA's inspection of the facilities of the Company's third-party manufacturer. Following a meeting with FDA to discuss the observations, the Company re-submitted the NDA for OFIRMEV on May 4, 2010. On November 2, 2010 the FDA approved OFIRMEV for the management of mild to moderate pain, moderate to severe pain with adjunctive opioid analgesics, and the reduction of fever in adults and children two years of age and older. In January 2011, the Company commenced commercial sales of the product in the U.S.

As of December 31, 2010, the Company was considered to be a development stage company as it had not generated any revenue from sales of OFIRMEV.

2. Summary of Significant Accounting Policies

Management Estimates

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

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, restricted cash, an option purchase right, equity securities of an unconsolidated privately-held entity, accounts payable, accrued liabilities and long-term debt. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, restricted cash, accounts payable and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The Company's option purchase right and equity securities of an unconsolidated privately-held entity have been initially valued based upon the transaction price under the cost method of accounting. These assets are subject to fair value adjustments in certain circumstances, such as when there is evidence of impairment. The fair value of marketable securities is based upon market prices quoted on the last day of the fiscal period.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

Current accounting guidance defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and requires certain disclosures about fair value measurements. The valuation techniques included in the guidance are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect market assumptions and are classified into the following fair value hierarchy:

- Level 1 Inputs* – Quoted prices for identical instruments in active markets.
- Level 2 Inputs* – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable.
- Level 3 Inputs* – Valuation derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

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

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

The Company's level 2 financial instruments are valued using market prices on less active markets. These valuations use pricing models that vary by asset class, incorporating such data as available trade information for similar securities, expected cash flows and credit information.

Cash Equivalents

The Company considers all highly liquid investments purchased with maturities of three months or less to be cash equivalents. These investments may include money market funds, U.S. Government agencies, corporate debt securities and commercial paper. As of December 31, 2010 and 2009, the Company's cash equivalents were \$112,111,000 and \$73,260,000, respectively.

Marketable Securities

The Company determines the appropriate classification of its investments at the time of acquisition and reevaluates such determination at each balance sheet date. The Company's investment policy set minimum credit

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

quality criteria and maximum maturity limits on its investments to provide for safety of principle, liquidity and a reasonable rate of return. Investments for which maturity from the balance sheet date is greater than one year are classified as long-term investments in marketable securities. Available-for-sale securities are recorded at fair value, based on current market valuations. Unrealized holding gains and losses on available-for-sale securities are excluded from earnings and are reported as a separate component of other comprehensive income until realized. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of the securities sold.

The Company has classified its investment holdings as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies. During the years ended December 31, 2009 and 2008, the Company recorded an impairment charge to reduce the value of an available-for-sale equity security by \$45,000 and \$177,000, respectively, as the market value was significantly below the security's carrying value. No such charges were incurred for the year ended December 31, 2010. See Note 3 for further discussion.

Concentration Risk

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

Manufacturing. The Company depends on an outsourced manufacturing strategy for its products. Currently, it relies upon a single source for the active pharmaceutical ingredient for OFIRMEV and has a single third-party manufacturer approved for production of the finished OFIRMEV drug product. The Company has entered into an agreement with a supplemental supplier, from which the Company may purchase OFIRMEV following FDA approval of that supplemental supplier's facility.

Segment Information

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

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.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

Royalty and License Payments

Pursuant to the terms of the license agreement with BMS, the Company is required to make royalty payments based upon net sales of OFIREV. The Company will accrue for these payments as the product is sold. Additionally, the Company paid \$15,000,000 under the license agreement upon the NDA approval of OFIRMEV in November 2010 and may be required to make future milestone payments of up to \$25,000,000 based the achievement of certain levels of net sales. The Company has capitalized the \$15,000,000 payment as an intangible asset on its balance sheet and will amortize this balance based upon product sales. The Company will accrue for future milestone payments as they are anticipated and amortize the payments over the period in which the milestone is achieved.

Advertising Expense

The Company records the cost of its advertising efforts when services are performed or goods are delivered. The Company incurred approximately \$828,000 in advertising costs for the year ended December 31, 2010 and for the period from inception through December 31, 2010. No advertising expense was incurred during the years ended December 31, 2009 and 2008. As of December 31, 2010, the Company capitalized \$30,000 of advertising costs in prepaid expenses. No prepaid advertising was capitalized as of December 31, 2009.

Property and Equipment

Property and equipment, including leasehold improvements, are stated at cost. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which are generally as follows: seven years for manufacturing equipment; five years for furniture and equipment; and three years for computer equipment and software. Leasehold improvements are amortized over the shorter of their useful lives or the terms of the related leases. Asset lives are reviewed periodically to determine if appropriate and adjustments are made as necessary. Depreciation begins at the time the asset is placed in service. Maintenance and repairs are expensed as incurred.

For the years ended December 31, 2010, 2009 and 2008, the Company recorded depreciation expense of \$758,000, \$537,000 and \$530,000, respectively. Since May 26, 2004 (inception) through December 31, 2010, the Company has incurred \$2,608,000 of depreciation expense.

Impairment of Long-Lived Assets

Long-lived assets such as property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or the fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposed group classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet.

During 2010, the Company recorded a charge of \$1,522,000 due to the modification of the design of the planned second production line for OFIRMEV, resulting in the partial cancellation of a capital equipment order for which the Company has identified an alternative supplier. Additionally, during the fourth quarter of 2008, the Company recorded an impairment charge of \$2,353,000 related to its omiganan pentahydrochloride manufacturing assets due to the discontinuation of the Company's development program for that product

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

candidate. During 2009, the Company recorded an adjustment to the impairment charge taken on the omigagan pentahydrochloride manufacturing equipment, reducing the charge by \$181,000, as actual costs incurred in disposing of the assets were less than anticipated. These impairment charges and adjustments are included in "Other" operating expenses on the Company's statement of operations for the years ended December 31, 2010, 2009 and 2008, respectively.

Research and Development

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

Income Taxes

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

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

Stock-Based Compensation

The Company has stock-based compensation plans, which are described in Note 10. As of December 31, 2010, the Company had issued both stock option awards and restricted stock units under its stock-based compensation plans.

Stock option awards. Stock options are valued using the Black-Scholes option pricing model on the date of grant. This option pricing model involves a number of estimates, including the expected lives of stock options,

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

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, 2010, 2009 and 2008, to determine the fair value of stock options granted during each period:

| | Year Ended December 31, | | |
|--------------------------------|-------------------------|-----------|-----------|
| | 2010 | 2009 | 2008 |
| Risk free interest rates | 2.7% | 2.2% | 2.9% |
| Expected life in years | 5.9 years | 6.0 years | 6.0 years |
| Expected dividend yield | 0.0% | 0.0% | 0.0% |
| Expected volatility | 76.3% | 71.6% | 70.0% |

The Company determines its risk-free interest rate assumption based on the U.S. Treasury yield for obligations with contractual lives similar to the expected lives of the Company's share-based payment awards being valued. The weighted-average expected life of options was calculated using the simplified method, as prescribed by the Securities and Exchange Commission ("SEC"), due to the lack of relevant historical exercise data. The Company anticipates it will continue to use the simplified method until such data is available. In addition, due to the Company's limited historical stock price volatility data, the estimated volatility is calculated by incorporating the historical volatility of comparable companies. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Forfeitures are estimated based upon the historical and anticipated future experience. Based upon these assumptions, the Company has estimated the per share weighted-average grant date fair value of its options granted for the years ended December 31, 2010, 2009 and 2008 at \$5.99, \$5.99 and \$4.13, respectively.

Restricted stock unit awards. Restricted stock units ("RSUs") are valued based on the fair market value of the Company's stock on the date of grant and the Company recognizes expense for RSUs if vesting is considered probable. The weighted-average grant date fair value of the RSUs granted in 2010 and 2009 was \$10.38 and \$10.91 respectively. There were no RSUs granted in 2008.

Compensation expense for all stock-based payment awards is recognized using the straight-line method. Stock-based compensation expense recognized during the period is based on the value of the portion of awards that is ultimately expected to vest. Hence, the gross expense is reduced for estimated forfeitures and adjusted for the probability of achieving performance criteria. 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, | | | Period from May 26, 2004 (Inception) through December 31, 2010 |
|---|-------------------------|----------------|----------------|--|
| | 2010 | 2009 | 2008 | |
| Research and development | \$ 3,058 | \$2,577 | \$1,967 | \$ 9,407 |
| Sales and marketing | 2,964 | 502 | 61 | 3,561 |
| General and administrative | 4,491 | 4,676 | 3,910 | 17,714 |
| Stock-based compensation expense included in operating expenses | 10,513 | 7,755 | 5,938 | 30,682 |
| Total stock-based compensation expense included in loss from operations | <u>\$10,513</u> | <u>\$7,755</u> | <u>\$5,938</u> | <u>\$30,682</u> |

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

The compensation expense related to unvested stock options and RSUs not yet recognized was approximately \$15,980,000 at December 31, 2010. 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, 2010, 2009 and 2008 was \$9,273,000, \$6,546,000 and \$6,340,000, respectively.

Comprehensive Income (Loss)

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

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 2010 and 2009 were excluded from the basic net loss calculation as these units do not include dividend rights and therefore are not considered to be participating securities.

The actual net loss per share amounts for the years ended December 31, 2010, 2009 and 2008 were computed based on the weighted average shares of common stock outstanding during the respective periods. The net loss per share for the years presented include the effect of the (i) 12,500,000 common shares issued pursuant to a public offering in the fourth quarter of 2010; (ii) 12,039,794 common shares issued pursuant to a private placement in the first quarter of 2009 and (iii) 9,240,307 common shares issued pursuant to an effective shelf registration in the first quarter of 2008. As a result of the issuance of these common shares, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented.

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

| | <u>Year Ended December 31,</u> | | |
|---|--------------------------------|---------------|---------------|
| | <u>2010</u> | <u>2009</u> | <u>2008</u> |
| Shares for basic and dilutive net loss per share: | | | |
| Weighted average common shares outstanding | 52,043 | 48,841 | 37,095 |
| Weighted average unvested common shares subject to repurchase | <u>(1)</u> | <u>(87)</u> | <u>(271)</u> |
| Denominator for basic and diluted earnings per share | <u>52,042</u> | <u>48,754</u> | <u>36,824</u> |

At December 31, 2010, 2009 and 2008, options, restricted stock units and warrants totaling approximately 13,460,000 shares, 11,446,000 shares and 3,851,000 shares, respectively, were excluded from the calculation as their effect would have been anti-dilutive.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

Recent Accounting Pronouncements

In December 2010, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2010-29, *Business Combinations (Topic 805): Disclosure of Supplementary Pro Forma Information for Business Combinations*. ASU 2010-29 is intended to address diversity in practice regarding pro forma revenue and earnings disclosure requirements for business combinations. This guidance specifies that if a public entity presents comparative financial statements, the entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. The guidance also expands the supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. ASU 2010-29 affects any public entity, as defined by Topic 805, that enters into business combinations that are material on an individual or aggregate basis. The guidance is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period after December 15, 2010. The Company will adopt the provisions of this guidance on January 1, 2011.

Also in December 2010, the FASB issued ASU No. 2010-28, *Intangibles—Goodwill and Other (Topic 350): When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts*. ASU 2010-28 amends Accounting Standards Codification (“ASC”) Topic 350 and affects all entities that have recognized goodwill and have one or more reporting units whose carrying amount for purposes of performing Step 1 of the goodwill impairment test is zero or negative. Under this guidance, when the carrying amount of a reporting unit is zero or negative an entity must assume that it is more likely than not that a goodwill impairment exists, perform an additional test to determine whether goodwill has been impaired and calculate the amount of that impairment. The qualitative factors are consistent with existing guidance, which requires that goodwill of a reporting unit be tested for impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. ASU 2010-28 is effective for fiscal years beginning after December 15, 2010 and early adoption is not permitted. The Company evaluated the provisions of this guidance and has determined that its adoption is not expected to have a material effect on its financial statements.

Additionally, the FASB issued ASU No. 2010-27, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers*, in December 2010. ASU 2010-27 addresses questions concerning how pharmaceutical manufacturers should recognize and classify in their income statement fees mandated by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act. Under this guidance, the liability for the fee should be estimated and recorded in full upon the first qualifying sale with a corresponding deferred costs that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable. The Company is evaluating the impact of the provisions of this guidance on its financial statements.

In April 2010, the FASB issued ASU No. 2010-12, *Income Taxes (Topic 740): Accounting for Certain Tax Effects of the 2010 Health Care Reform Acts*. This update clarifies questions surrounding the accounting implications of the different signing dates of the Health Care and Education Reconciliation Act and the Patient Protection and Affordable Care Act (the “Acts”). ASU 2010-12 states that the FASB and the Office of the Chief Accountant at the SEC would not be opposed to viewing the two Acts together for accounting purposes. The Company evaluated the provisions of this guidance and the adoption of this guidance did not have a material impact on its financial statements.

CADENCE PHARMACEUTICALS, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

3. Investments in Marketable Securities

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

At the time of acquisition the Migenix stock, these shares were recorded at an initial cost of \$450,000 and in 2005 and 2004, the Company recognized non-cash impairment charges on the shares of \$183,000 and \$45,000, respectively, related to decreases in the market value of the Migenix stock that were considered to be other-than-temporary. In 2008, the Company recorded an additional other-than-temporary impairment charge of \$177,000 to further reduce the book value of the Company's equity security position in its Migenix holding to the current fair value and in 2009, the Company recorded a charge of \$45,000 to impair the remaining balance of the security holding after the Company discontinued its omiganan pentahydrochloride program. These charges are included in "Other" non-operating expense on the Company's statement of operations for the years ended December 31, 2009 and 2008, respectively. No similar impairment charges were recorded for the year ended December 31, 2010.

The cost, gross unrealized holding gains, gross unrealized holding losses and fair value of available-for-sale investments by types and classes of security at December 31, 2010 and December 31, 2009 consisted of the following (in thousands):

| <u>At December 31, 2010</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> |
|---|---------------------------------|--|---|--|-------------------|
| Available-for-sale: | | | | | |
| Debt instruments—Municipal debt obligations | \$15,466 | \$— | \$— | \$— | \$15,466 |
| Debt instruments—Corporate debt obligations | 5,500 | — | — | — | 5,500 |
| Certificates of deposit | 1,000 | — | — | — | 1,000 |
| | <u>\$21,966</u> | <u>\$—</u> | <u>\$—</u> | <u>\$—</u> | <u>\$21,966</u> |
| | | | | | |
| <u>At December 31, 2009</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> |
| Available-for-sale: | | | | | |
| Debt instruments—U.S. Government agencies | \$ 6,147 | \$— | \$ 1 | \$ (1) | \$ 6,147 |
| | <u>\$ 6,147</u> | <u>\$—</u> | <u>\$ 1</u> | <u>\$ (1)</u> | <u>\$ 6,147</u> |

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

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

| | December 31, 2010 | | December 31, 2009 | |
|---|-------------------|------------|-------------------|------------|
| | Cost | Fair Value | Cost | Fair Value |
| Due or callable in one year or less | \$21,966 | \$21,966 | \$6,147 | \$6,147 |
| Due after one year | \$ — | \$ — | \$ — | \$ — |

4. Selected Financial Statement Data

| | As of December 31, | |
|---|--------------------|-----------------|
| | 2010 | 2009 |
| Inventory (in thousands): | | |
| Raw materials | \$ 68 | \$ — |
| Finished goods | 417 | — |
| Total | <u>\$ 485</u> | <u>\$ —</u> |
| Property and equipment (in thousands): | | |
| Manufacturing equipment | \$ 4,016 | \$ — |
| Leasehold improvements | 1,610 | 1,610 |
| Computer equipment and software | 1,505 | 841 |
| Furniture and fixtures | 455 | 469 |
| Construction-in-process | 3,813 | 7,060 |
| | <u>11,399</u> | <u>9,980</u> |
| Less accumulated depreciation | (2,413) | (1,680) |
| Total | <u>\$ 8,986</u> | <u>\$ 8,300</u> |
| Accrued liabilities (in thousands): | | |
| Accrued personnel costs | \$ 3,987 | \$ 2,876 |
| Accrued manufacturing costs and equipment purchases | 562 | 3,361 |
| Other accrued liabilities | 2,737 | 1,524 |
| Total | <u>\$ 7,286</u> | <u>\$ 7,761</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 to acquire Incline during two option periods, and has additional rights after the expiration of the second period. Incline is developing IONSYSTM (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery.

In consideration for the option, the Company paid Incline a \$3,500,000 upfront option fee and will pay Incline a second \$3,500,000 fee upon Incline receiving the second tranche of its Series A financing if the Company has not yet exercised its option to acquire Incline. During the first option period, the Company may acquire Incline for an amount not to exceed \$135,000,000. During the second option period, the Company may acquire Incline for an amount not to exceed \$228,000,000, plus payment of an additional amount not to exceed \$57,000,000 upon FDA approval of IONSYSTM.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

The first option period, which commenced on June 21, 2010, extends through the later to occur of (1) 12 months or (2) one day prior to the date on which Incline receives the second tranche of its Series A financing. The second option period commences on the expiration of the first option period and extends until the earliest to occur of (a) 30 days after the date on which Incline submits a supplemental NDA for IONSYS to the FDA, (b) 30 days after the filing of an initial public offering by Incline, or (c) 42 months. The Company has an exclusive right of first negotiation to acquire Incline for the six-month period following the expiration of the second option period and may elect to extend the second option period for two additional three-month periods upon the payment of \$2,500,000 to Incline for each period. During the option periods, Incline will remain primarily responsible for the development of IONSYS. However, the Company and Incline have formed a joint development committee to oversee the global development and regulatory approval for the IONSYS product candidate.

The Company has determined that Incline is a variable interest entity (“VIE”), however because it will not absorb a disproportionate amount of Incline’s expected losses or receive a disproportionate amount of Incline’s expected residual returns, the Company is not the primary beneficiary of this entity at this time. Further, Cadence will have no oversight of the day-to-day operations of Incline, nor does it have sufficient rights or voting representation to influence the operating or financial decisions of Incline. Additionally, the Company was not a founder of Incline and has no additional equity or funding requirements in future financings or otherwise. Therefore, the Company is not required to consolidate Incline into its financial statements. This consolidation status could change in the future if the option agreement is exercised, or if other changes occur in the relationship between the Company and Incline. Frazier Healthcare VI, L.P. owns approximately 22.1% of Incline’s Series A Preferred Stock. Alan D. Frazier, one of the Company’s directors, has an ownership interest in Frazier Healthcare VI, L.P., and is a member of the general partner of the entity that serves as general partner of Frazier Healthcare VI, L.P.

In consideration of the Company’s expenditure of funds in connection with conducting due diligence on IONSYS, the Company received \$500,000 of Incline Series A preferred stock, or 500,000 shares, on terms generally consistent with Incline’s other Series A preferred stock investors. The Company valued the transaction using the cost method, assigning \$500,000 to the preferred stock and \$3,000,000 to the option. Under the cost method, the fair value of the investment is not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment. As of December 31, 2010, the Company was not aware of any such adverse effects. As a result, no fair value estimate has been prepared with respect to this investment as the costs associated with an independent evaluation would be excessive and the available information on which to base such an assessment is both limited and highly subjective. Both assets are recorded as other long-term assets on the Company’s balance sheet at December 31, 2010. No similar assets were recorded at December 31, 2009.

6. Omiganan Pentahydrochloride Restructuring and Impairment Charges

In March 2009, the Company announced its decision to discontinue the development of its omiganan pentahydrochloride product candidate. This decision was due to the failure of the Company’s Phase III clinical trial of omiganan pentahydrochloride to meet its primary endpoint and the Company’s belief that the results of this clinical trial would not support an NDA submission. In connection with the discontinuation of this development program, the Company implemented a corporate restructuring in order to reduce, and eventually eliminate, associated costs, including the termination of 11 employees. The Company recorded impairment charges in the fourth quarter of 2008 of \$2,353,000 with respect to certain omiganan pentahydrochloride manufacturing equipment, based upon management estimates of the salvage value of the equipment at the time the impairment charge was taken. Further, the Company recorded restructuring charges of \$651,000 in the first quarter of 2009 for severance-related costs and the termination of contractual obligations, based upon management estimates of the termination costs at the time they were recorded.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

The Company recorded adjustments to the impairment charge taken on the manufacturing equipment in 2009, reducing the charge by an aggregate \$181,000 during 2009 as actual costs incurred in disposing of the assets were less than anticipated. Additionally, adjustments totaling \$64,000 were recorded to the severance obligation during 2009 and are included in the Company's "Other" operating expenses on the statement of operations. As of December 31, 2009, no liability remained for severance-related costs and termination of contractual obligations.

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

| | Year Ended December 31, | | | Period from May 26, 2004 (Inception) through December 31, 2010 |
|--|-------------------------|------------|------------|--|
| | 2010 | 2009 | 2008 | |
| Beginning restructuring liability | \$— | \$— | \$— | \$— |
| Severance and termination charges incurred | — | 651 | — | 651 |
| Adjustments to severance and termination charges | — | (64) | — | (64) |
| Severance and termination disbursements | — | (587) | — | (587) |
| Ending restructuring liability | <u>\$—</u> | <u>\$—</u> | <u>\$—</u> | <u>\$—</u> |

7. Loan and Security Agreement

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

In November 2007, the Company amended the Agreement and entered into the Second Amendment to Loan and Security Agreement (the "Second Amendment") with the same parties and GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.) (collectively, the "lenders"), to secure an additional \$15,000,000 loan facility. In December 2007, the Company drew down \$15,000,000 under the Second Amendment in two separate draws of \$5,000,000 and \$10,000,000 with fixed interest rates of 7.83% and 7.74%, respectively, net of a \$45,000 loan fee (the "loan fee"). In addition to the principal and interest, the Company was required to pay \$375,000 at the termination of the Second Amendment (the "term loan final payment"). In June 2010, the Company entered into an Amended and Restated Loan and Security Agreement (the "Restated Agreement") with the same lenders. The Restated Agreement amends and restates the Company's existing Agreement and provided the Company with a new \$30,000,000 growth capital loan facility, available to the Company in two advances. The first advance of \$20,000,000 was made in conjunction with securing the facility in June 2010 at a fixed interest rate of 11.33%. The second advance of \$10,000,000 was made available upon approval by the FDA of OFIRMEV and was drawn in the November 2010 at a fixed interest rate of 10.08%. The Company paid an upfront fee of \$300,000 and reimbursed the lenders for their expenses incurred in initiating the loan. The Company will also be required to make a growth capital final payment of \$1,800,000 at the termination of the Restated Agreement. Further warrants, as described below, were issued as part of the transaction.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

In connection with the establishment of the \$30,000,000 facility, the outstanding balance of the \$15,000,000 facility was paid in full, including accrued interest, and the \$375,000 term loan final payment. Upon the repayment of the \$15,000,000 facility, the Company recorded a charge of approximately \$145,000 in the second quarter of 2010 to (i) fully amortize the balance of the loan discount and related issuance costs and (ii) fully accrue the term loan final payment. The Company will make interest-only payments on the outstanding balance of the Restated Agreement through July 1, 2011, and subsequently make principal and interest payments to fully amortize the balance over the remaining 30 month term.

The warrants issued and the upfront fees paid in connection with the Restated Agreement, have been recognized as a discount on the loan issuance. The legal and related expenses have been recognized as debt issuance costs on the Company's balance sheet which, together with the warrants, upfront fee, growth capital final payment and fixed interest rate, will be amortized to interest expense throughout the life of the loan using an effective interest rate of 15.95%. The loans are collateralized by substantially all the assets of the Company (excluding intellectual property). Under the terms of the Restated Agreement, the Company may be precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and is subject to certain non-financial covenants and prepayment penalties. Upon the occurrence of an event of default, including a Material Adverse Change (as defined in the Restated Agreement), the lenders may declare all outstanding amounts due and payable under the Agreement. As of December 31, 2010, the Company was in compliance will all covenants under the Restated Agreement.

As of December 31, 2010 and 2009, the aggregate principal balance of the loans, net of the loan discounts, included on the Company's balance sheets was \$28,677,000 and \$6,442,000, respectively. Future maturities under the Company's Restated Agreement as of December 31, 2010 were as follows (in thousands):

| | |
|--|------------------------|
| 2011 | \$ 7,646 |
| 2012 | 13,766 |
| 2013 | 13,766 |
| 2014 | 2,947 |
| 2015 | — |
| Total future payments | 38,125 |
| Less amount representing interest and fees | <u>(8,125)</u> |
| Gross balance of long-term debt | 30,000 |
| Less unamortized discount | <u>(1,323)</u> |
| Total present value of long-term debt | <u><u>\$28,677</u></u> |

Warrants

In connection with the Second Amendment, the Company issued six fully exercisable warrants to the lenders to purchase an aggregate of 50,331 shares of the Company's common stock at an exercise price of \$12.67 per share, expiring November 30, 2014. The Company determined the fair value of these warrants to be \$474,000 under the Black-Scholes valuation model using the following assumptions: risk-free interest rate of 3.64%; dividend yield of 0.0%; expected volatility of 70.0%; and a contractual term of seven years. As of December 31, 2010, all warrants related to the Second Amendment were outstanding.

In connection with the Restated Agreement, the Company issued three fully exercisable warrants to the lenders to purchase an aggregate of 254,793 shares of the Company's common stock at an exercise price of

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

\$7.0645 per share, expiring June 18, 2017. The Company determined the relative fair value of these warrants to be \$1,237,000, using the Black-Scholes valuation model. The value of the warrants was recorded as a discount to the note payable, and will be amortized to interest expense over the expected term of the loan agreement. The warrants were valued using the following assumptions: risk-free interest rate of 2.7%; dividend yield of 0.0%; expected volatility of 76.5%; and a contractual term of seven years. As of December 31, 2010, all warrants related to the Restated Agreement were outstanding.

8. Commitments and Contingencies

Leases

In May 2006, the Company entered into a six-year operating lease for 23,494 square feet of office space. The Company received certain tenant improvement allowances and rent abatement and has an option to extend the lease for five years following the expiration of the initial term. Monthly rental payments are adjusted on an annual basis and the lease expires in September 2012. As security for the lease, a letter of credit in the initial amount of \$1,581,000 was required by the landlord. The letter of credit is collateralized by a certificate of deposit in the same amount that is classified as restricted cash in the Company's balance sheet. The required amount subject to the letter of credit and corresponding certificate of deposit may be reduced by 22% on each of the first four anniversaries of the commencement of the lease. As of December 31, 2010, the letter of credit had been reduced by \$1,391,000 in accordance with the agreement and the related restricted cash had been adjusted by a like amount. The value of the letter of credit and corresponding certificate of deposit, classified as restricted cash on the Company's balance sheet at December 31, 2010 was \$190,000.

In January 2007, the Company entered into a sublease agreement for a portion of its unused office space. The sublease agreement expired in September 2009 and the Company has since recaptured the space to support its growth. The Company also leases certain office equipment under operating leases with original terms that range from one to four years and expire in 2012. As of December 31, 2010, the total future minimum payments under operating leases, including rent and office equipment, were as follows (in thousands):

| | |
|------------------|---------|
| 2011 | \$1,219 |
| 2012 | 934 |
| 2013 | — |
| 2014 | — |
| 2015 | — |
| Thereafter | — |
| | \$2,153 |

Rent expense for operating leases is recorded on a straight-line basis over the life of the lease term. If a lease has a fixed and determinable escalation clause, the difference between the rent expense and rent paid is recorded as deferred rent. Rent expense, net of sublease rent income, for the years ended December 31, 2010, 2009 and 2008 was \$859,000, \$653,000 and \$568,000, respectively. Since May 26, 2004 (inception) through December 31, 2010, the Company has incurred net rent expense of \$3,634,000.

Corporate Credit Card

In 2009, the Company entered into a pledge agreement pursuant to the establishment of a corporate credit card program whereby the Company pledged \$150,000 in a certificate of deposit as collateral. These funds are

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

therefore classified as restricted cash on the Company's balance sheet at December 31, 2010 and 2009, respectively.

Supply Agreements

Baxter Healthcare Corporation

In July 2007, the Company entered into a development and supply agreement (the "Supply Agreement") with Baxter Healthcare Corporation ("Baxter") for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of the finished drug product for OFIRMEV with an initial term of five years. Pursuant to the terms of the Supply Agreement, Baxter received development fees from the Company upon the completion of specified development activities, which the Company expensed as these activities had no alternative future uses at the time they were incurred. During the years ended December 31, 2010 and 2008, the Company paid Baxter approximately \$754,000 and \$1,400,000, respectively, in development fees. No development fees were paid during 2009. The Supply Agreement also required the Company to fund specified improvements at Baxter's manufacturing facility and purchase certain equipment for use by Baxter in manufacturing OFIRMEV. During the years ended December 31, 2010, 2009 and 2008, the Company had reimbursed Baxter approximately \$1,813,000, \$952,000, and \$1,374,000, respectively, for the facility improvements, which were also expensed as the costs were incurred. Certain equipment purchased for the manufacture of OFIRMEV to which the Company retains title, has been capitalized.

In January 2011, the Company amended and restated the Supply Agreement (the "Amended Supply Agreement") in connection with plans to expand the manufacturing capacity for OFIRMEV at Baxter. Similar to original Supply Agreement, all capital equipment and facility improvements included in the plan will be funded by the Company. The Company intends to capitalize these costs, as OFIRMEV has been approved by the FDA, however the Company is not able to reasonably estimate the cost of expansion until the capacity increase development plan is completed. Further, the Company will pay Baxter a per unit purchase price based on the amount of finished OFIRMEV drug product produced, which price will be increased annually, and may be adjusted to reflect an increase or decrease, as the case may be, in the cost of material required to manufacture OFIRMEV, subject to specified limitations. The Company is obligated to purchase a minimum number of units of OFIRMEV each year or pay Baxter an amount equal to the purchase price multiplied by the shortfall in units. In addition, Baxter will be the Company's primary supplier of OFIRMEV up to a specified number of units in each year, subject to Baxter's ability to timely supply the specified volumes required by the Company. However, if Baxter fails or declines to supply a sufficient quantity of OFIRMEV in accordance with the Company's purchase orders during a specified period of time, then the Company may purchase that OFIRMEV from third party suppliers and such quantity will be deducted from the quantity of OFIRMEV that the Company otherwise would have been required to purchase from Baxter. The Company is also obligated to reimburse Baxter for all reasonable costs directly related to work performed by Baxter in support of any change in the active pharmaceutical ingredient ("API") source or API manufacturing process.

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

commercially produce, for itself or for any third party, any intravenous formulation of a product containing acetaminophen for distribution or sale in the United States.

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

In anticipation of the execution of the original Supply Agreement, the Company entered into an irrevocable standby letter of credit in favor of Baxter in January 2007. The letter of credit was for an initial amount of \$3,268,000 and was based on anticipated costs to be incurred by Baxter for the improvements at Baxter's manufacturing facility and the purchase of equipment to be used by Baxter in the manufacturing of the finished drug product. This letter of credit was collateralized by a certificate of deposit and classified as restricted cash on the Company's balance sheet. As of December 31, 2010, the letter of credit had expired and all restrictions were released.

Lawrence Laboratories

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

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

The Supplemental Agreement has an initial term that ends upon the 36-month anniversary of the date the sNDA is approved by the FDA, unless the Supplemental Agreement is terminated sooner: (1) by mutual agreement of the parties, (2) by either party for convenience following eighteen months' prior written notice of termination to the other party, (3) upon the termination of the Company's license agreement for the product with BMS, or (4) upon the dissolution or termination of the Company, other than in connection with or following the assignment of the Supplemental Agreement. In addition, either party may terminate the Supplemental Agreement: (a) within 60 days after written notice in the event of a material uncured breach of the Supplemental

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

Agreement by the other party, or (b) immediately, if the other party becomes insolvent or admits in writing its inability to pay its debts as they become due, files a petition for bankruptcy, makes an assignment for the benefit of its creditors or has a receiver or other court officer appointed for its properties or assets.

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

Minimum purchase requirements under the Company's supply agreements as of December 31, 2010 were as follows (in thousands):

| | |
|-------------|-----------------|
| 2011 | \$ 1,740 |
| 2012 | 3,410 |
| 2013 | 3,260 |
| 2014 | 3,320 |
| 2015 | <u>3,380</u> |
| Total | <u>\$15,110</u> |

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"). As consideration for the license, the Company paid a \$25,000,000 up-front fee and, as a result of the approval of the Company's NDA for OFIRMEV in the fourth quarter of 2010, the Company was required to make an additional milestone payment of \$15,000,000 during the period. The Company may be required to make future milestone payments totaling up to \$25,000,000 upon the achievement of certain levels of net sales. In addition, the Company is obligated to pay a royalty on net sales of the licensed products and has the right to grant sublicenses to third parties. The amount of such royalty ranges from the mid-teens to the mid-twenties, depending on the aggregate amount of net sales. 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 payment is being recorded as an intangible asset on the Company's balance sheet and amortized over the estimated life of the patent.

As a result of the discontinuation of the Company's omiganan pentahydrochloride development program, on May 8, 2009, the collaboration and license agreement between the Company and Migenix for this product candidate was terminated. No charges were incurred from the termination of this agreement.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

10. Stockholders' Equity

Public Offering

In November and December 2010, the Company issued an aggregate of 12,500,000 shares of its common stock at a purchase price of \$8.00 per share pursuant to a public offering. The offering raised proceeds, net of offering costs and underwriting discounts and commissions, of \$93,554,000.

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. As of December 31, 2010, all warrants related to the private placement were outstanding.

The private placement raised proceeds, net of offering costs, of \$86,243,000. The purchasers in the offering consisted of new investors and existing stockholders of the Company, including six funds affiliated with three directors of the Company. In March 2009, the Company filed a registration statement covering the resale of the shares of common stock acquired by the investors in this offering, which was declared effective by the SEC in May 2009. The Company is required to maintain the effectiveness of the registration statement and may be subject to liquidated damages of one percent per month of the aggregate purchase price of the common shares then held by the investor that are registrable securities, subject to an aggregate cap of eight percent per calendar year. The Company has not recorded a liability for the potential damages associated with these liquidated damages provisions, as it does not currently believe that the transfer of consideration is probable under the agreement.

Equity Awards

In 2006, the Company adopted the 2006 Equity Incentive Award Plan (the "2006 Plan") in connection with the Company's initial public offering which became effective on October 24, 2006. Upon adoption of the 2006 Plan, the Company restricted future grants from its 2004 Equity Incentive Award Plan (the "2004 Plan"). The 2006 Plan was amended and restated in 2010 to preserve the ability to deduct compensation associated with future performance-based awards made under the plan to certain executives. The term of the 2006 Plan was also extended under the 2010 amendment to 2020.

The 2006 Plan initially reserved 2,100,000 shares of common stock for future issuance and allowed for the initial number of reserved shares to be increased by (i) the 90,772 shares of common stock that remained available for issuance under the 2004 Plan as of the effective date of the 2006 Plan and (ii) the number of shares under the 2004 Plan that are repurchased, forfeited, expired or cancelled on or after the effective date of the 2006 Plan. As of December 31, 2010, options to purchase 74,753 shares issued under the 2004 Plan have been repurchased, forfeited and/or cancelled since the effective date of the 2006 Plan, increasing the number of shares reserved for issuance under the 2006 Plan accordingly.

Beginning on January 1, 2008, the 2006 Plan allows for an annual increase in the number of shares available for issuance under the 2006 Plan by the lesser of (i) 4% of the outstanding common stock on January 1 and (ii) a lesser amount determined by the board of directors, subject to an aggregate of 20,000,000 shares of common

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

stock that may be issued through January 1, 2016. At January 1, 2010, 2009 and 2008, the board of directors approved the amount of shares authorized for future issuance under the 2006 Plan to be increased by 1,766,960 shares, 1,269,576 shares and 1,018,939 shares, respectively, under this provision.

As of December 31, 2010, the Company had issued both stock options and restricted stock units under the 2006 Plan and only stock options under the 2004 Plan. The following table presents shares authorized, available for future grant and outstanding under each of the Company's plans at December 31, 2010:

| | <u>Authorized</u> | <u>Available</u> | <u>Outstanding</u> |
|----------------------------------|-------------------|------------------|--------------------|
| 2004 Equity Incentive Plan | 2,709,475 | — | 1,399,089 |
| 2006 Equity Incentive Plan | 6,321,000 | 563,584 | 5,736,226 |
| | <u>9,030,475</u> | <u>563,584</u> | <u>7,135,315</u> |

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

Stock Options

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

The following table summarizes the Company's stock option activity as of December 31, 2010, and changes for the year then ended:

| | <u>Shares</u> | <u>Weighted-Average Exercise Price</u> | <u>Weighted-Average Remaining Contractual Life - Years</u> | <u>Aggregate Intrinsic Value</u> |
|--|------------------|--|--|--|
| Options outstanding at beginning of period | 5,217,738 | \$7.32 | | |
| Granted | 2,101,275 | \$8.90 | | |
| Exercised | (119,531) | \$1.99 | | |
| Cancelled | (199,825) | \$8.72 | | |
| Options outstanding at end of period | <u>6,999,657</u> | <u>\$7.84</u> | <u>7.48</u> | <u>\$9,394,000</u> |
| Options exercisable at end of period | <u>3,968,921</u> | <u>\$7.04</u> | <u>6.47</u> | <u>\$8,884,000</u> |

The aggregate intrinsic value of options exercised during 2010, 2009 and 2008 was \$792,000, \$700,000 and \$72,000, respectively.

Restricted Stock Units

In August 2009, the Company granted a total of 300,500 RSUs to certain officers and employees. One-half of the RSUs were to vest upon the approval by the FDA of the NDA for OFIRMEV, if such approval occurred

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

prior to December 31, 2009. At December 31, 2009, the Company had not received approval of its OFIRMEV NDA and therefore the performance criteria for these grants was not achieved. As such, the awards were forfeited and all previously recorded expense associated with these RSUs was recovered. The remaining half of the RSUs, adjusted for cancellations from terminations, are to vest upon the first anniversary of the approval by the FDA of the NDA for OFIRMEV, or November 2, 2011, and remained outstanding as of December 31, 2010. An additional 13,500 RSUs were granted in 2010, of which a portion had vested as of December 31, 2010. The RSUs that continue to be outstanding as of December 31, 2010 had an intrinsic value of \$1,024,000.

The following table summarizes the Company's RSU activity as of December 31, 2010, 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 | 149,750 | \$10.91 | |
| Granted | 13,500 | \$10.38 | |
| Vested | (4,217) | \$10.38 | |
| Cancelled | (23,375) | \$10.91 | |
| Restricted stock units outstanding at end of period | <u>135,658</u> | <u>\$10.87</u> | <u>\$1,024,000</u> |

The aggregate intrinsic value of RSUs vested during 2010 was \$33,000. There was no vesting of RSUs in 2009 and 2008, respectively.

11. Income Taxes

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company's tax years for 2004 and forward are subject to examination by the Federal and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrued interest and/or penalties related to income tax matters in the Company's balance sheets at December 31, 2010 and 2009, and has recognized no interest and/or penalties in the Company's statement of operations for the years ended December 31, 2010, 2009 and 2008, respectively.

The Company adopted the provisions of ASC 740, *Accounting for Uncertainty in Income Taxes*, on January 1, 2008. On the date of adoption, there were no unrecognized tax benefits and thus the Company did not recognize an increase in the liability for unrecognized tax benefits. Further, there are no unrecognized tax benefits in the Company's balance sheets at December 31, 2010 and 2009, respectively.

The Company has not completed an Internal Revenue Code Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Until this analysis has been completed, the Company has removed the deferred tax assets for net operating losses of approximately \$89,176,000 and research and development credits of approximately \$5,679,000 generated through 2010 from its deferred tax asset schedule, and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits accordingly. The Company does not expect this analysis to be completed within the next 12 months and, as a result, the Company does not expect that the unrecognized tax benefits will change within 12 months of this reporting date. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

A valuation allowance has been established as realization of such deferred tax assets has not met the more likely than not threshold requirement. Other significant components of the Company's deferred tax assets for federal and state income taxes at December 31, 2010 and 2009 are shown below (in thousands):

| | <u>As of December 31,</u> | |
|---|---------------------------|---------------|
| | <u>2010</u> | <u>2009</u> |
| Deferred tax assets: | | |
| Net operating loss carryforwards | \$ — | \$ — |
| Tax credit carryforwards | — | — |
| Stock-based compensation | 9,007 | 5,851 |
| Capitalized research and development | 7,115 | 7,963 |
| Other, net | 2,302 | 2,165 |
| | <u>18,424</u> | <u>15,979</u> |
| Valuation allowance for deferred tax assets | (18,424) | (15,979) |
| 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:

| | <u>As of December 31,</u> | | |
|--|---------------------------|-------------|-------------|
| | <u>2010</u> | <u>2009</u> | <u>2008</u> |
| Federal income taxes | 35.0% | 35.0% | 35.0% |
| State income taxes | 5.8% | 5.8% | 5.8% |
| Research and development credits | 1.0% | 2.4% | 3.5% |
| Stock-based compensation | (1.7)% | (1.7)% | (1.2)% |
| Change in federal valuation allowance | (4.3)% | (5.9)% | (1.7)% |
| Prior year true-up | 0.3% | 2.3% | — |
| Removal of net operating loss and research and development tax credits | (35.7)% | (37.4)% | (41.1)% |
| Other, net | (0.4)% | (0.5)% | (0.3)% |
| | <u>0.0%</u> | <u>0.0%</u> | <u>0.0%</u> |

At December 31, 2010, the Company had federal and state net operating loss carryforwards of approximately \$219,334,000 and \$224,650,000, respectively. The federal and state tax loss carryforwards will begin to expire in 2024 and 2018, respectively, unless previously utilized. The Company also had federal research and development tax credit carryforwards of approximately \$4,227,000 which will begin expiring in 2024 unless previously utilized, and state research and development tax credit carryforwards of approximately \$2,233,000 which carryforward indefinitely.

Included in the net operating loss carryforwards is approximately \$693,000 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.

12. 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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

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 2010, 2009 and 2008, the Company elected not to make any contributions to the plan.

13. 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, 2010 and 2009 are as follows (in thousands, except share and per share data):

| | Fiscal Year 2010 Quarters | | | | Total |
|--|----------------------------------|--------------------------|--------------------------|------------|--------------|
| | 1st | 2nd⁽³⁾ | 3rd⁽³⁾ | 4th | |
| Total operating expenses | \$ 13,759 | \$ 11,885 | \$ 11,087 | \$ 18,186 | \$ 54,917 |
| Net loss | \$(13,919) | \$(12,219) | \$(11,712) | \$(18,793) | \$(56,643) |
| Basic and diluted net loss per share ⁽¹⁾⁽²⁾ | \$ (0.28) | \$ (0.24) | \$ (0.23) | \$ (0.33) | \$ (1.09) |

| | Fiscal Year 2009 Quarters | | | | Total |
|--|----------------------------------|------------|------------|------------|--------------|
| | 1st⁽⁴⁾ | 2nd | 3rd | 4th | |
| Total operating expenses | \$ 10,138 | \$ 8,003 | \$ 11,295 | \$ 15,061 | \$ 44,497 |
| Net loss | \$(10,437) | \$ (8,301) | \$(11,441) | \$(15,312) | \$(45,491) |
| Basic and diluted net loss per share ⁽¹⁾⁽²⁾ | \$ (0.24) | \$ (0.17) | \$ (0.23) | \$ (0.30) | \$ (0.93) |

- (1) Loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly net loss per share may not necessarily equal the total for the year.
- (2) In the fourth quarter of 2010 and first quarter of 2009, the Company issued 12,500,000 shares and 12,039,794 shares, respectively, of common stock. As a result, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented.
- (3) During the second and third quarters of 2010, the Company recorded charges of \$1,186 and \$336, respectively, related to the partial cancellation of an equipment order.
- (4) During the first quarter of 2009, the Company recorded a restructuring charge of \$651 related to the discontinuation of its omiganan pentahydrochloride development program. This charge was reduced by \$64 as of December 31, 2009 as the actual costs incurred were less than anticipated.

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

Not applicable.

Item 9A. *Controls and Procedures*

Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934, as amended, (the "Exchange Act") is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. Management has determined that there were no significant changes to our internal control over financial reporting during the year or quarter ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

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

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the company's financial statements.

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

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

As of December 31, 2010, 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, 2010 and is included below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited Cadence Pharmaceuticals, Inc.'s (a development stage company) internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Cadence Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Cadence Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, 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, 2010 and 2009, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2010 and for the period from May 26, 2004 (Inception) through December 31, 2010, of Cadence Pharmaceuticals, Inc. and our report dated March 4, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 4, 2011

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, 2010 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, 2010 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, 2010 pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference. The information required this item regarding our equity compensation plan is included in 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, 2010 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, 2010 pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report:

(1) *Financial Statements*. The following financial statements of Cadence Pharmaceuticals, Inc., together with the report thereon of Ernst & Young LLP, required to be filed pursuant to Part II, Item 8 of this Annual Report on Form 10-K, are included on pages 61 through 88, as follows:

| | <u>Page</u> |
|--|-------------|
| Report of Independent Registered Public Accounting Firm | 61 |
| Balance Sheets at December 31, 2010 and 2009 | 62 |
| Statements of Operations for the years ended December 31, 2010, 2009 and 2008, and for the period from May 26, 2004 (inception) through December 31, 2010 | 63 |
| Statements of Stockholders' Equity for the years ended December 31, 2010, 2009, 2008, 2007, 2006 and 2005, and for the period from May 26, 2004 (inception) through December 31, 2004 | 64 |
| Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008, and for the period from May 26, 2004 (inception) through December 31, 2010 | 66 |
| Notes to Financial Statements | 67 |

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

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

(b) Exhibits.

| <u>Exhibit Number</u> | <u>Description of Exhibit</u> |
|---------------------------|--|
| 3.1 | Amended and Restated Certificate of Incorporation of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006 |
| 3.2 | Amended and Restated Bylaws of the Company, incorporated herein by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006 |
| 3.3 | Amendment of Amended and Restated Bylaws of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 17, 2007 |
| 4.1 | Form of the Company's Common Stock Certificate, incorporated herein by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006 |
| 4.2 | Amended and Restated Investor Rights Agreement dated February 21, 2006, incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006 |
| 4.3 | Registration Rights Waiver and Amendment dated November 29, 2007, incorporated herein by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007 |
| 4.4 | Form of Warrant to Purchase Stock issued to Silicon Valley Bank on November 30, 2007, incorporated herein by reference to Exhibit 4.6 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007 |

| <u>Exhibit Number</u> | <u>Description of Exhibit</u> |
|-----------------------|--|
| 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 |
| 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# | Second Amended and Restated Cadence Pharmaceuticals, Inc. Director Compensation Policy, incorporated herein by reference to Exhibit 10.27 to the Company's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2008 as filed with the SEC on November 7, 2008 |
| 10.3# | Form of Second Amended and Restated Employment Agreement, incorporated herein by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K (File No. 001-33103) for the year ended December 31, 2008 as filed with the SEC on March 16, 2009 |
| 10.4# | Employment Agreement between the Company and Scott A. Byrd, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on June 22, 2009 |
| 10.5# | 2004 Equity Incentive Award Plan and forms of Option Agreements thereunder, incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-8 (File No. 333-138226) as filed with the SEC on October 26, 2006 |
| 10.6# | 2010 Amendment and Restatement of the 2006 Equity Incentive Award Plan, incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-8 (File No. 333-138226) as filed with the SEC on December 23, 2010 |
| 10.7 | Forms of Option and Restricted Stock Agreements under the 2006 Equity Incentive Award Plan, incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-8 (File No. 333-138226) as filed with the SEC on October 26, 2006 |
| 10.8# | Form of Deferral Restricted Stock Unit Agreement under the 2006 Equity Incentive Award Plan, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on September 2, 2009 |
| 10.9# | Form of Non-Deferral Restricted Stock Unit Agreement under the 2006 Equity Incentive Award Plan, incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on September 2, 2009 |

| Exhibit Number | Description of Exhibit |
|-----------------------|---|
| 10.10# | 2010 Corporate Bonus Plan, incorporated herein by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K (File No. 001-33103) for the year ended December 31, 2009 as filed with the SEC on March 15, 2010 |
| 10.11# | 2011 Corporate Bonus Plan |
| 10.12 | Form of Amended and Restated Restricted Common Stock Purchase Agreement, incorporated herein by reference to Exhibit 10.6 to Amendment No. 1 of the Company's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on August 30, 2006 |
| 10.13 | Form of Common Stock Purchase Agreement dated February 14, 2008, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 15, 2008 |
| 10.14 | Securities Purchase Agreement, dated February 13, 2009, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 20, 2009 |
| 10.15 | Lease dated May 12, 2006 by and between the Company and Prentiss/Collins Del Mar Heights LLC, incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006 |
| 10.16† | 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 |
| 10.17† | 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 |
| 10.18† | Supply Agreement dated December 1, 2010 by and between the Company and Lawrence Laboratories, an indirect wholly-owned subsidiary of Bristol-Myers Squibb Company, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 2, 2010 |
| 10.19† | Amended and Restated Development and Supply Agreement by and between the Company and Baxter Healthcare Corporation dated January 28, 2011, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 2, 2011 |
| 10.20† | 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 |
| 10.21 | 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 |
| 10.22† | Option Agreement dated June 21, 2010 by and among the Company and Incline Therapeutics, Inc., incorporated herein by reference to Exhibit 10.37 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 |

| Exhibit Number | Description of Exhibit |
|-----------------------|---|
| 23.1 [±] | Consent of Independent Registered Public Accounting Firm |
| 31.1 [±] | Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 [±] | Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1 [±] | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 |

[±] Included in this Report.

[#] Indicates management contract or compensatory plan.

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

SIGNATURES

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

CADENCE PHARMACEUTICALS, INC.

By: /s/ THEODORE R. SCHROEDER

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

Dated: March 4, 2011

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

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|--|---------------|
| /s/ THEODORE R. SCHROEDER Theodore R. Schroeder | President, Chief Executive Officer and Director (Principal Executive Officer) | March 4, 2011 |
| /s/ WILLIAM R. LARUE William R. LaRue | Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary (Principal Financial and Accounting Officer) | March 4, 2011 |
| /s/ CAM L. GARNER Cam L. Garner | Chairman of the Board of Directors | March 4, 2011 |
| /s/ BRIAN G. ATWOOD Brian G. Atwood | Director | March 4, 2011 |
| /s/ SAMUEL L. BARKER, PH.D. Samuel L. Barker, Ph.D. | Director | March 4, 2011 |
| /s/ MICHAEL A. BERMAN, M.D. Michael A. Berman, M.D. | Director | March 4, 2011 |
| /s/ JAMES C. BLAIR, PH.D. James C. Blair, Ph.D. | Director | March 4, 2011 |
| /s/ ALAN D. FRAZIER Alan D. Frazier | Director | March 4, 2011 |
| /s/ MICHAEL L. EAGLE Michael L. Eagle | Director | March 4, 2011 |
| /s/ TODD W. RICH Todd W. Rich | Director | March 4, 2011 |
| /s/ CHRISTOPHER J. TWOMEY Christopher J. Twomey | Director | March 4, 2011 |

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Corporate Directory

EXECUTIVE OFFICERS

Theodore R. Schroeder
President & Chief Executive Officer
Co-founder, Cadence Pharmaceuticals, Inc.

William R. LaRue
Senior Vice President
Chief Financial Officer, Treasurer &
Assistant Secretary

James B. Breitmeyer, M.D., Ph.D.
Executive Vice President, Development &
Chief Medical Officer

Scott A. Byrd
Senior Vice President &
Chief Commercial Officer

Hazel M. Aker, J.D.
Senior Vice President
General Counsel & Secretary

Malcolm Lloyd-Smith
Senior Vice President
Regulatory Affairs and Quality Assurance

BOARD OF DIRECTORS

Cam L. Garner
Chairman of the Board
Co-founder, Cadence Pharmaceuticals, Inc.

Brian G. Atwood
Managing Director
Versant Ventures

Samuel L. Barker, Ph.D.
Co-founder & Principal
Clearview Projects, Inc.

Michael A. Berman, M.D.
President & Chief Executive Officer
Michael A. Berman Group, Inc.

James C. Blair, Ph.D.
Partner
Domain Associates, L.L.C.

Michael L. Eagle
Vice President, Manufacturing
Eli Lilly (Retired)

Alan D. Frazier
Co-founder & Managing Partner
Frazier Healthcare

Todd W. Rich, M.D.
Senior Vice President and Global Head of
Clinical Operations and Quality
Genentech, Inc.

Theodore R. Schroeder
President & Chief Executive Officer
Co-founder, Cadence Pharmaceuticals, Inc.

Christopher J. Twomey
Senior Vice President Finance
& Chief Financial Officer
Biosite Incorporated (Retired)

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP
4370 La Jolla Village Drive, Suite 500
San Diego, California 92122

TRANSFER AGENT

American Stock Transfer and Trust Co.
59 Maiden Lane, Plaza Level
New York, New York 10038

WEBSITE

www.cadencepharm.com

STOCK LISTING

Symbol: CADX
Exchange: The Nasdaq Global Market

CORPORATE HEADQUARTERS

12481 High Bluff Drive, Suite 200
San Diego, California 92130
Telephone: (858) 436-1400
Facsimile: (858) 436-1401
info@cadencepharm.com

INVESTOR SERVICES

A copy of the company's 2010 Annual Report on Form 10-K, including the financial statements and the financial statement schedules, which is filed with the Securities and Exchange Commission, is available without charge for download at www.cadencepharm.com or upon request to:

Investor Relations

Cadence Pharmaceuticals, Inc.
12481 High Bluff Drive, Suite 200
San Diego, California
Telephone: (858) 436-1400

FORWARD-LOOKING STATEMENTS

Statements included in this Annual Report that are not a description of historical facts are forward-looking statements. Words such as "plans," "believes," "expects," "anticipates," and "will," and similar expressions, are intended to identify forward-looking statements, and are based on our current beliefs and expectations. Such statements include, without limitation, statements regarding: the anticipated U.S. market opportunity for IV acetaminophen, our ability to achieve formulary and market acceptance for OFIRMEV, our strategy for building a long-term hospital pain franchise, the sufficiency of our capital resources to fund our operations, and our financial estimates or projections. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Our actual future results may differ materially from our current expectations due to the risks and uncertainties inherent in our business. These risks include: our dependence on the successful commercialization of OFIRMEV; the potential that delays in achieving formulary acceptance for OFIRMEV at a substantial number of targeted accounts may enable competitors to further entrench their products and decrease the market potential for OFIRMEV; our ability to ensure an adequate and continued supply of OFIRMEV to meet anticipated market demand; the potential that we may fail to comply with numerous federal, state and local laws and regulatory requirements that apply to our commercial activities, including the promotion and sale of pharmaceutical products; public concern regarding the safety of drug products such as OFIRMEV, which 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; our ability to successfully enforce our marketing exclusivities, intellectual property rights and defend our patents; the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of intravenous acetaminophen; the potential product liability exposure associated with pharmaceutical products such as OFIRMEV and other products we may in-license or acquire, and the substantial liability we may face if successful product liability claims are brought against us; the risk that we may not be able to raise sufficient capital when needed; and other risks detailed under "Risk Factors" and elsewhere in our periodic reports and our other filings made with the Securities and Exchange Commission from time to time. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995, and we undertake no obligation to revise or update this Annual Report to reflect events or circumstances after the date hereof.

ANNUAL MEETING

The annual stockholders meeting will be held on Wednesday, June 15, 2011 at 8:00 a.m., at the Homewood Suites by Hilton Hotel, 11025 Vista Sorrento Parkway, San Diego, California 92130



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