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2008 ANNUAL REPORT

May 6, 2009

Dear Cadence Stockholders,

Despite a challenging economic environment during the latter half of 2008, we successfully achieved several key corporate objectives during the year and made significant progress towards our goal of establishing Cadence Pharmaceuticals as a leading hospital-focused biopharmaceutical company.

Importantly, we substantially advanced the development of Acetavance™, our proprietary, intravenous formulation of acetaminophen, completing and announcing the results of five Phase III clinical trials during 2008. We began 2008 by announcing in January that our Study 302 of Acetavance successfully met its primary endpoint, demonstrating a statistically significant reduction of fever over six hours compared to placebo. At the same time, we announced the results of Study 301, our Phase III clinical trial to evaluate Acetavance in the treatment of pain following abdominal gynecologic surgery. While Study 301 did not achieve its primary efficacy endpoint, it importantly demonstrated a safety profile of Acetavance similar to placebo. In May 2008, we announced that Study 303, another of our Phase III clinical trials of Acetavance in adults, successfully met its primary endpoint of achieving a more rapid onset of action in the treatment of experimentally-induced fever compared to oral acetaminophen. We closed the year by announcing in December that Study 304, a Phase III clinical trial of Acetavance for the treatment of acute pain in adults following abdominal laparoscopic surgery, successfully met its primary endpoint of a statistically significant reduction in summed pain intensity differences from baseline over 24 hours compared to placebo and that Study 351, a clinical trial evaluating the safety of repeated doses of Acetavance in adults, demonstrated a hepatic and general safety profile of Acetavance comparable standard of care. Additionally, in July 2008, we received written guidance from the U.S. Food and Drug Administration, or FDA, regarding the pivotal clinical trial requirements for the submission of a New Drug Application, or NDA, for Acetavance.

We completed our clinical development program for Acetavance in the first quarter of 2009 and, during the second quarter of this year, we anticipate the completion of perhaps our most significant objective to date – the submission of the Acetavance NDA for the treatment of acute pain and fever in adults and children.

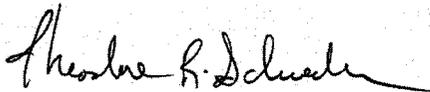
During 2008, we completed our goal of enrolling 1,850 patients in our Phase III clinical CLIRS trial of Omigard™, our product candidate for the prevention of catheter-related infections. In March 2009, we announced that the CLIRS trial did not meet its primary endpoint and made the strategic decision to discontinue further development of Omigard and implement a number of related cost-reduction measures. While we are disappointed in the outcome of our Omigard development program, we believe that we can continue to enhance the near and long-term value of our company by focusing our resources on Acetavance.

We strengthened the company's balance sheet in February 2008 by raising gross proceeds of \$49.3 million in a registered direct offering of approximately 9.2 million shares of common stock. In the first quarter of 2009, we continued to ensure that we have the financial resources required to complete our product development and pre-commercialization activities by raising additional gross proceeds of \$86.6 million in a private placement of approximately 12.0 million shares of common stock and five-year warrants to purchase up to approximately 6.0 million additional shares of common stock.

Our company's leadership team was strengthened in 2008 by the addition of Malcolm Lloyd-Smith as our Senior Vice President, Regulatory Affairs and Quality Assurance and the appointment of Todd Rich, M.D., to our board of directors. One of our key objectives in 2009 will be to begin to assemble a team of highly qualified individuals with experience in the U.S. hospital market to form the basis of our commercial organization in preparation for the launch of Acetavance, if approved by the FDA.

On behalf of our Board of Directors and all of the employees at Cadence, thank you for your continued support of Cadence Pharmaceuticals as we prepare for what we believe will be an exciting year ahead.

Sincerely,



Theodore R. Schroeder
President, Chief Executive Officer and Director

**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, 2008

or

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

Commission File Number 001-33103

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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 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, 2008, the last business day of the Registrant's second fiscal quarter, reported on the NASDAQ Global Market, was approximately \$123,042,695. 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 27, 2009, there were 50,403,779 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 2009 Annual Meeting of Stockholders, which is scheduled to be held on June 24, 2009. 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, 2008.

Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, and the information incorporated herein include forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Forward-looking statements discuss matters that are not historical facts, and include, but are not limited to, discussions regarding our business, regulatory and commercialization strategies, growth strategy, competition, industry, regulatory environment, economic conditions, financial condition, liquidity and capital resources and results of operations. In this Annual Report, for example, we make forward-looking statements regarding the potential for Acetavance™ to receive regulatory approval; the results of analyses of clinical trials of Acetavance conducted by us and others, and our expectations as to whether those results will be sufficient to support regulatory approval of Acetavance; our ability to successfully commercialize Acetavance; the scope and validity of patent protection for Acetavance, and our ability to commercialize this product candidate without infringing the patent rights of others; our expectations regarding competition, pricing and market acceptance of Acetavance; and projections regarding our anticipated financial position and operating requirements. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words, “believe,” “may,” “might,” “can,” “could,” “will,” “would,” “should,” “estimate,” “continue,” “anticipate,” “intend,” “seek,” “plan,” “project,” “expect,” or similar expressions.

While we believe that the expectations reflected in this Annual Report are reasonable, the inclusion of any forward-looking statements should not be regarded as a representation that any of our plans will be achieved. Our actual results will differ from those anticipated in our forward looking statements as a result of various factors, including those set forth below under the caption “Item 1A.—Risk Factors,” and the differences may be material. These risk factors include, but are not limited to: our dependence on the success of our only product candidate, Acetavance, and on our ability to obtain regulatory approval for, and successfully commercialize, this product candidate on a timely basis; the adequacy of the clinical trial and other data we plan to submit in our applications for regulatory approval to support the safety and efficacy of Acetavance; our reliance on third parties to assist us with our regulatory submissions and other important aspects of our product development programs, and the risk that the performance of those third parties may be substandard or delayed; the potential that changes made in scaling-up or transferring the manufacturing processes for Acetavance may result in a lack of comparability between our commercial product and the material used in our clinical trials, which could delay regulatory approval of this product candidate and substantially increase our costs; our reliance on our contract manufacturer to timely complete pre-commercialization manufacturing development activities, comply with stringent regulatory requirements and, if Acetavance is approved and commercialized, to produce Acetavance in the volumes that we require; the potential that Acetavance may be found to have undesirable side effects that could delay or prevent its regulatory approval or commercialization; the impact of recent publicity concerning the safety of certain drug products, which has resulted in heightened scrutiny by the FDA in the process of approving new drugs and which could delay or limit any regulatory approvals we may obtain; the impact of the intense competition we expect for Acetavance on its commercial potential, and whether any new products may emerge that provide different or better therapeutic alternatives for our targeted indications; the limitations of the patent rights covering Acetavance, and the possibility that our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient; and our requirements for substantial additional funding and potential inability to raise capital when needed, which would force us to delay, reduce or eliminate our development programs and commercialization efforts.

For those statements, we claim the protection of the safe harbor for forward-looking statements contained in Section 21E of the Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date on which they were made. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

CADENCE PHARMACEUTICALS, INC.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2008

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PART I

Item 1. *Business*

Company Overview

We are a biopharmaceutical company focused on in-licensing, developing and commercializing product candidates principally for use in the hospital setting. Since our inception in May 2004, we have in-licensed rights to two late-stage product candidates, Acetavance™, a proprietary intravenous formulation of acetaminophen, and Omigard™, or omiganan pentahydrochloride 1% aqueous gel.

We in-licensed the exclusive United States, or U.S., and Canadian rights to Acetavance from Bristol-Myers Squibb Company, or BMS, which markets this product candidate in Europe and other markets for the treatment of acute pain and fever under the brand name *Perfalgan*®. We in-licensed the exclusive rights to commercialize Omigard in North America and Europe in July 2004, and we devoted substantial efforts to the development of this product candidate from that time until March 2009, when we announced the discontinuation of this program due to the failure of our Phase III clinical trial to meet its primary endpoint.

We believe that Acetavance may fulfill significant unmet needs in the hospital setting. We also believe that the hospital pharmaceuticals market is both concentrated and underserved, which may enable us to build our own hospital-focused sales force if Acetavance achieves U.S. Food and Drug Administration, or FDA, approval. We intend to build a leading franchise in the hospital setting, continuing to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations.

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

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

Our Business Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of proprietary pharmaceuticals principally for use in the hospital setting. Our near-term strategy is to focus on completing the development and commercialization of Acetavance. Our longer-term strategy is to in-license, acquire, develop and commercialize additional product candidates that are in late-stages of development, currently commercialized outside the U.S. or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations. Specifically, we intend to:

- *Obtain regulatory approval for our product candidate, Acetavance* We have applied the expertise of our development teams to conduct and successfully complete the clinical trials and other development activities associated with Acetavance, continually refine our Phase III clinical program for this product candidate in light of new information that we receive in an effort to reduce clinical development risk, facilitate regulatory approval and optimize marketing claims. We currently expect to submit a New Drug

Application, or NDA, for Acetavance in the second quarter of 2009 based on our own clinical trials of this product candidate in the U.S., the trials previously completed by BMS in the U.S. and Europe, and other studies of intravenous acetaminophen published in the scientific and medical literature.

- *Build a highly leverageable sales organization targeting hospitals* We intend to build a commercial organization focused on promoting our products principally to hospitals in the U.S. We believe that Acetavance can be effectively promoted by our own sales force. Importantly, the number of institutions comprising the hospital marketplace is relatively limited, and we believe a small number of these institutions account for a substantial portion of the prescribing activity. The concentrated nature of this market creates the opportunity for significant marketing synergies as we intend to 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 our products in areas where we have commercialization rights.
- *Expand our product portfolio through acquiring or in-licensing additional late-stage, hospital-focused products with well-understood risk profiles* We will seek additional opportunities to acquire or in-license products to continue to exploit our clinical, regulatory, manufacturing, sales and marketing capabilities. We believe that our focus on the hospital market enables us to evaluate a broader range of products across multiple therapeutic areas for possible acquisition. In addition, competition from large pharmaceutical companies has generally diminished in the hospital marketplace as their emphasis has shifted toward larger opportunities in the outpatient setting. To reduce the time to market and the risks and costs of clinical development, we 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 our product candidates* We will seek to maximize the value of Acetavance and any other product candidates we may in-license, acquire or develop by pursuing other indications and commercial opportunities for such candidates.

ACETAVANCE™

Product Overview

We are developing Acetavance, a proprietary intravenous formulation of acetaminophen, for the U.S. market for the treatment of acute pain and fever in adults and children. In its oral form, acetaminophen is the most widely used drug for the treatment of pain and fever in the U.S. Acetaminophen was discovered in the late 19th century and was made available for sale in 1955 when it was introduced in the U.S. under the brand name Tylenol. Acetaminophen is currently available in over 600 combination and single-ingredient prescription and over-the-counter medicines, including tablet, caplet, orally-dosed liquid suspension, powder and suppository forms for both adults and children. Despite the broad usage of acetaminophen, there is no intravenous formulation currently available in the U.S. for patients who are unable to take medications by mouth, require faster onset of pain relief or fever reduction, or for whom it is otherwise more convenient to receive an injectable analgesic.

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

Unmet Need in the Treatment of Acute Pain and Fever

Acute Pain

Acute pain is generally defined as pain that arises quickly, may be severe in nature, and is relatively short-lived. The duration of acute pain is usually measured in days to a few weeks, rather than several weeks to months

as is chronic pain. In the hospital setting, acute pain is generally classified as post-operative or non-operative. Despite major improvements in surgical techniques and the introduction of novel drugs, the overall treatment of post-operative acute 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 acute 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 acute pain, which may increase the risk of deep venous thrombosis, reduced lung tidal volume, and partial collapse or incomplete inflation of the lungs, as well as potentially prolonging hospital stays. All of these factors have the potential to significantly impact patient care and create additional costs for hospitals.

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

The only non-opioid intravenous analgesic currently available in the U.S. is the NSAID ketorolac. NSAIDs act as non-selective inhibitors of the enzyme cyclooxygenase, inhibiting both the cyclooxygenase-1, or COX-1, and cyclooxygenase-2, or COX-2, enzymes. The inhibition of COX-2 produces an anti-inflammatory effect resulting in analgesia. Since NSAIDs do not produce respiratory depression or impair gastrointestinal motility, they are considered to be useful alternatives or adjuncts to opioids for the relief of acute pain.

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

Fever

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

Hospitalized patients are at especially high risk for developing fever due to the prevalence of infections, whether community- or hospital-acquired, and as a result of invasive procedures and treatments that may cause fevers. Surgery is the most common predisposing factor for fever in the hospital setting, with published incidence rates ranging from 14% to 91% of post-operative patients. Infections such as surgical wound infections, urinary tract infections, and pneumonia are the most common causes of post-operative fevers. However, deep venous thrombosis, pulmonary emboli, myocardial infarction, transfusions of blood products, and medications are also important potential causes of post-operative fever. Many patients also enter hospitals and emergency rooms with fevers that 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. Ibuprofen is not approved for children less than six months of age and is not recommended for patients who are dehydrated or vomiting continuously. Aspirin is contraindicated in children and teenagers with viral infections due to the risk of acquiring Reye's syndrome, a potentially fatal disease.

Treating fever in a hospitalized patient with oral medication may be difficult or not feasible due to the severe nausea and vomiting that often accompany a high fever, or because the patient is unconscious, sedated, fasting or experiencing gastrointestinal dysfunction. Oral medications are also precluded in patients on a restricted oral intake regimen due to a concomitant medical condition or upcoming medical procedure. In the U.S., neither acetaminophen, ibuprofen, nor aspirin are available in intravenous dosage forms. While rectal delivery of these medications is sometimes possible, drug absorption using this method may be highly variable, resulting in the potential for inadequate levels of efficacy. Rectal delivery is further complicated if the drug is expelled with a bowel movement, which leads to difficulty determining the amount of medication delivered. This is a particular issue for neonates and infants. As a result, pediatric dosing guidance for rectally administered acetaminophen calls for higher loading doses and higher daily maximum doses than for orally administered acetaminophen, which may place some neonates and infants at risk for toxicity if the drug is absorbed at a level greater than expected. Therapeutic drug levels often may be achieved more rapidly when a drug is administered intravenously compared to oral or rectal administration, offering the potential advantage of a more rapid onset of action. This may be particularly desirable in patients with high fever, or in whom fever is causing undesirable symptoms or complications such as febrile seizures. It may also be more convenient to administer medications in an intravenous dosage form, particularly for patients who currently have an intravenous line in place. We believe that the availability of Acetavance in the U.S. would offer a significant new treatment option for hospitalized patients with fever and address unmet medical needs.

Multi-Modal Acute 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. There are no intravenous COX-2 inhibitors approved in the U.S. and the only approved intravenous NSAID carries a black box warning for the risk of bleeding, renal dysfunction, and other adverse effects. Acetaminophen has not been associated with these risks, and the ASA guidelines state that acetaminophen is believed to have a dose-sparing effect for systematically administered opioids. Therefore, we believe that Acetavance is well positioned to become the foundation of a multi-modal pain management regimen in the immediate post-operative setting to be used as the around-the-clock analgesic. In such a regimen, opioids and NSAIDs would only be used adjunctively, on an as-needed basis, to meet any additional pain management requirements.

The concept of using acetaminophen for multi-modal management of acute 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 #3 (codeine plus acetaminophen), Ultram (tramadol plus acetaminophen), and Darvocet (propoxyphene plus acetaminophen). Since an intravenous formulation of acetaminophen has not been available in the U.S., physicians have not been able to extend this common multi-modal approach to the peri-operative setting, when patients are not able to take oral medications.

Sales Performance of Intravenous Acetaminophen in Europe

Intravenous acetaminophen is marketed by BMS outside of the U.S. and Canada under the brand name Perfalgan. This product is currently approved in approximately 80 countries and is marketed throughout Europe and other parts of the world. Intravenous acetaminophen was launched on a country-by-country basis, beginning in France in 2002, followed by Germany and Spain in 2003, and Italy and the United Kingdom in 2004. Based on 2007 data from IMS Health, Inc., or IMS, an independent marketing research firm, we estimate that more than 350 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 80 million units sold, or approximately \$200 million in product sales, in 2007. This performance corresponds to an estimated market share in Europe in 2007 of 21% of all injectable analgesic units, and an estimated 45% market share of all injectable analgesic dollar sales. In some European Union, or E.U., countries, such as France and Belgium, intravenous acetaminophen has a unit market share greater than 40% based on 2007 data from IMS. We believe these and other countries are utilizing intravenous acetaminophen as the foundation for multi-modal analgesia, particularly in the post-operative setting.

U.S. Market Opportunity

We believe that the U.S. market represents a potentially larger sales opportunity for intravenous acetaminophen than Europe with respect to potential unit market share and pricing. We estimate that the U.S. market is comparable to the European market when viewed from the perspective of the number of days of analgesic therapy administered to patients annually, which is calculated based on equivalent doses of the various therapeutic options. Based on sales reported to IMS in 2007, we have estimated that analgesic equivalent doses represented approximately 90 million analgesic patient days in the E.U., compared to approximately 80 million patient days in the U.S. The E.U. analgesic therapy market consists of intravenous opioids, NSAIDs and acetaminophen. While there is only one injectable NSAID currently available in the U.S., there are multiple intravenous NSAIDs available in Europe. According to IMS, 291 million vials of injectable analgesics were sold in the U.S. in 2008. Morphine is the current market leader and accounted for more than 163 million vials sold in 2008. More than 90 million vials of other injectable opioids, such as meperidine, hydromorphone and fentanyl, which are all available in generic forms, were sold in 2008. Toradol, or ketorolac, an NSAID that is available as a generic drug, is the only non-opioid intravenous injectable analgesic available for treating acute pain in adults in the U.S. According to IMS, more than 38 million vials of injectable ketorolac were sold in the U.S. in 2008.

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 2007 was approximately \$2.50 (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 contrast, 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.

We believe that the key product attributes that will drive the adoption of Acetavance in the U.S. market include the proven efficacy and established safety profile of oral acetaminophen, the potential for reducing concomitant use of morphine and other opioids, and the need for a more convenient dosage form for patients unable to take medication orally and a more rapid onset of action. In a market survey by IMS commissioned by us in 2007, 81% of the 126 U.S. physicians surveyed indicated readiness to use intravenous acetaminophen immediately following the product's approval by the FDA.

Clinical Development

We intend to submit a 505(b)(2) NDA for Acetavance seeking an indication for the treatment of acute pain and fever in adults and children. Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. Supportive information may also include scientific literature and publicly available information contained in the labeling of other medications. Our NDA for Acetavance will include data from our own clinical trials in the U.S., trials of intravenous acetaminophen previously completed by BMS in the U.S. and Europe, and other studies published in the scientific and medical literature. Approximately 2,000 patients have received intravenous acetaminophen in clinical trials conducted by us or others to date.

New Drug Application (NDA) Requirements

Since we in-licensed the rights to intravenous acetaminophen in March 2006, we have had communications with the FDA to discuss the NDA requirements for this product candidate, including an End of Phase II meeting in August 2006. We also received written guidance from the FDA in July 2008 stating that one post-operative pain trial previously completed by our licensor BMS and one fever trial completed by us would be sufficient to meet the pivotal clinical trial requirements for the submission of an NDA for Acetavance for the treatment of acute pain and fever. Based on this FDA guidance, our clinical development plan consists of:

- two pivotal, Phase III clinical trials to demonstrate the efficacy of intravenous acetaminophen in adults, one in pain and one in fever,
- safety data from a Phase III clinical trial in adults following abdominal gynecologic surgery,
- two safety studies, one in adults, and one in children, and
- two pharmacokinetic studies, one in adults and one in children.

With the successful completion of the last of our clinical studies in adults, the adult portion of our clinical development plan for Acetavance has been completed. We have also successfully completed our pharmacokinetic study in children, and have completed enrollment in our open-label safety study of Acetavance in children. This pediatric safety study is the last remaining required trial in our clinical development plan for this product candidate and, assuming the successful completion of our remaining development activities, we currently plan to submit an NDA for Acetavance in the second quarter of 2009.

The following table summarizes the clinical trial data that we plan to include in our NDA submission as the basis of approval for Acetavance:

<u>Study</u>	<u>Number of Patients</u>	<u>Trial Design</u>	<u>Trial Outcome</u>
<i>Pivotal Efficacy Studies</i>			
RC 210 3 002 /Sinatra Study(BMS)	101	Hip and knee replacement	Sum of pain intensity differences over 24 hours (SPID24) superior for intravenous acetaminophen compared to placebo p<0.0001
Cadence Study 302	60	Endotoxin-induced fever	Weighted sum of temperature differences over 6 hours (WSTD6) p<0.001
<i>Adult Safety and Pharmacokinetics Studies</i>			
Cadence Study 351	213	Five day safety	Safety comparable to standard of care
Cadence Study 101	38	Pharmacokinetics of intravenous vs. oral acetaminophen	Demonstrated lack of accumulation over 48 hours
<i>Additional Adult Safety Data</i>			
Cadence Study 301	331	Abdominal gynecologic surgery	Safety comparable to placebo over 48 hours
<i>Pediatric Safety and Pharmacokinetics Studies</i>			
Cadence Study 102	75	Pharmacokinetics	Pharmacokinetics in children and adolescents comparable to adults; age-related reduction in clearance in newborns
Cadence Study 352	100	Five day safety	Enrollment completed

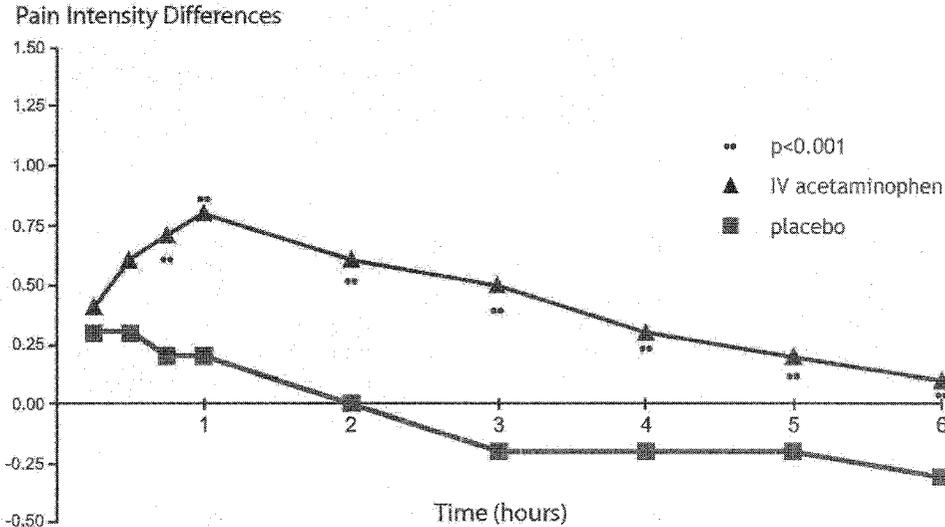
P-values indicate the likelihood that clinical trial results were due to random statistical fluctuations rather than a true cause and effect. The lower the p-value, the more likely there is a true cause-and-effect relationship. Therefore, p-values provide a sense of the reliability of the results of the study in question. Typically, the FDA requires a p-value of less than 0.05 to establish the statistical significance of a clinical trial.

Pivotal Clinical Trials Supporting Efficacy in Adult Patients

The pivotal clinical trials supporting the efficacy of our product candidate as are as follows:

- *RC 210 3 002, a Phase III clinical trial in adults with moderate-to-severe pain following total knee and hip replacement surgery.* This trial, which was completed by BMS, was a randomized, placebo-controlled, double-blind, multi-center Phase III study to assess the efficacy and safety of multiple doses of intravenous acetaminophen versus intravenous propacetamol or placebo. The primary efficacy endpoint of time-specific pain relief scores from 15 minutes to six hours was statistically significant (p<0.05) in favor of intravenous acetaminophen compared to placebo at all time points. Key secondary endpoints of time-specific pain intensity differences through six hours, weighted sum of pain intensity differences over six hours, weighted sum of pain relief differences over six hours, time to administration of the first rescue medication, patient global evaluation at 24 hours, and rescue medication consumption over 24 hours, were all statistically significant (p<0.05) in favor of intravenous acetaminophen compared to placebo. There was a 33% reduction in the amount of opioid used as rescue medication in the group treated with IV acetaminophen, and yet they reported a superior

pain experience, as indicated by the global satisfaction rating. In addition to the results originally reported, we have performed a re-analysis of the data from this trial using endpoints that the FDA currently favors for acute pain studies. Based upon our re-analysis of the sum of pain intensity differences over 24 hours, or SPID24, intravenous acetaminophen was shown to be superior to placebo ($p < 0.0001$). The following graph presents the pain intensity differences from the baseline measurements reported by patients in this study at each time point from 15 minutes to six hours:



Study RC 210 3 002 also demonstrated a statistically significant improvement in patient satisfaction with pain treatment for patients who received intravenous acetaminophen compared to placebo. The study results indicate that nearly twice as many subjects noted good or excellent results at 24 hours compared to placebo. The number of drug-related adverse events reported for the group of patients who received intravenous acetaminophen in this trial was similar to the number of events reported for the placebo group. After the study was completed, we analyzed the results using endpoints that are currently considered standard by the FDA for pain trials and found that Acetavance was superior to placebo for pain reduction over 24 hours (Sum of Pain Intensity Differences, or SPID). The table below provides a summary of these data from the trial:

	IV acetaminophen	IV placebo	p-value
SPID over 24 hours	0.4	-235	<0.0001
Weighted sums of pain relief over six hours	6.6	2.2	<0.05
Good/excellent global evaluation at 24 hours	41%	23%	<0.01
Rescue medication (morphine) consumption over 24 hours (mg)	38.3 (33% decrease)	57.4	<0.001
Safety	IV acetaminophen not significantly different than placebo		

- Cadence Study 302, a Phase III clinical trial in adults with fever.* This trial was a randomized, controlled, double-blind, double-dummy study to assess the efficacy and safety of a single dose of Acetavance compared to placebo. In January 2008, we announced that this study successfully met the primary endpoint, demonstrating a statistically significant reduction of fever over six hours compared to placebo ($p < 0.001$). Trial results will be presented at a scientific conference in the near future.

Clinical Trials Supporting Safety and Pharmacokinetics in Adult Patients

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

We believe that intravenous acetaminophen does not pose an increased risk for hepatotoxicity or any other adverse event when compared to equivalent doses of oral acetaminophen. In the approximately 2,000 subjects who received intravenous acetaminophen in clinical trials conducted to date, the product candidate has exhibited a safety profile consistent with published data for oral acetaminophen. An analysis of data from nine placebo-controlled, single and repeated dose trials conducted in more than 1,000 adults with acute postoperative pain or fever demonstrated that intravenous acetaminophen has a hepatic safety profile comparable to placebo, with liver function test elevations reported as a treatment-emergent adverse event in 6.3% of subjects who received placebo compared to only 3.1% of subjects who received intravenous acetaminophen.

In pharmacokinetic trials, the average peak plasma concentration of acetaminophen was briefly higher for intravenous acetaminophen when compared to the same dose of oral acetaminophen, but levels over time were not meaningfully different. These trials also demonstrated that Acetavance does not accumulate over multiple doses after 12 hours and that urinary elimination of acetaminophen metabolites, including metabolites with potential to interact with the liver, was not meaningfully different for intravenous acetaminophen compared to oral acetaminophen at 12 and 24 hour measurements. These studies concluded that intravenous acetaminophen would not be expected to be associated with an increased risk of toxicity to the liver compared with an equivalent dose of acetaminophen administered orally.

We plan to submit to the FDA data from the following clinical trials to support the safety and the pharmacokinetic profile of Acetavance in adults:

- *Cadence Study 301, a Phase III clinical trial in adult patients with moderate-to-severe pain following gynecologic surgery.* This clinical trial was a randomized, placebo-controlled, double-blind, multi-center study to assess the safety and efficacy in adult, female patients of single and multiple doses of Acetavance versus placebo over a 48-hour period. In this study, in which 331 patients were enrolled, the number of adverse events in the group of patients that received Acetavance was comparable to the group of patients in the placebo arm. There were no clinically relevant differences in adverse event reports over the 48-hour study period, and the follow-up at day seven, between Acetavance and placebo patients in the frequency of serious, severe, related, hepatic or overall adverse events. There was no evidence of local venous irritation or infusion-related pain with Acetavance. The frequency of quantitative liver enzyme elevations (alanine aminotransferase or aspartate aminotransferase), while comparable between the treatment groups, was more than twice as high in the placebo group as compared to the Acetavance group. We believe that this study did not meet its primary efficacy endpoint of demonstrating a statistically significant reduction in patients' pain intensity scores over 48-hours compared to placebo due to the much higher than predicted variability of the initial pain assessments, particularly in patients whose participation in the study commenced closer to the end of surgery. This variability had a large, negative impact on the baseline-dependent statistical measurements. However, several secondary endpoints, which were not as dependent on baseline pain measurement, were successfully achieved, including the sum of pain relief scores over 24 and 48 hours, global patient satisfaction at 24 and 48 hours, and time to administration of another analgesic medication.
- *Cadence Study 351, a Phase III safety study in adult patients.* This clinical trial, which was designed to evaluate the safety of repeated doses of Acetavance in adults for up to five days, was an open-label, multi-center study of 213 hospitalized patients randomized to receive repeated doses of Acetavance 1000mg every six hours, Acetavance 650mg every four hours, or standard of care treatment. In this

trial, the hepatic and general safety profile of the group of patients that received Acetavance was comparable to the standard of care treatment group, with numerically lower proportions of patients with elevated liver function tests in the two Acetavance groups compared to the standard of care treatment group.

- *Cadence Study 101, a pharmacokinetic study in adult patients.* This clinical trial was a randomized, single-center study to assess the pharmacokinetics in adults of single and multiple doses of Acetavance compared to oral acetaminophen. The results of this trial demonstrated that Acetavance produced a mean first dose maximum plasma concentration that was briefly up to approximately 75% higher than oral acetaminophen. However, overall drug exposure, which is also known as the area under the curve, was essentially the same for Acetavance and oral acetaminophen. The maximum plasma concentration for intravenous acetaminophen occurred at the end of the 15 minute infusion and occurred 30 minutes earlier than the observed maximum value for oral acetaminophen. The elimination half-life and volume of distribution values were comparable and not significantly different across treatment groups. Oral acetaminophen was 94% bioavailable in this study, indicating there should not be a need for physicians to convert their preferred dosage amounts when they switch between Acetavance and oral acetaminophen. Steady state levels of acetaminophen were achieved rapidly, as no drug accumulation occurred from 12 to 48 hours with repeated dosing. As expected, neither intravenous acetaminophen nor oral acetaminophen had a significant effect on platelet aggregation. There were no significant differences observed between the intravenous and oral acetaminophen groups with respect to the number of adverse events, including adverse hepatic events.

Clinical Trials Supporting Safety and Efficacy in Pediatrics

In order to support the safety and efficacy of Acetavance in pediatric patients, we plan to submit to the FDA data demonstrating comparable pharmacokinetics between children and adults from the following clinical trials:

- *Cadence Study 102, a pharmacokinetic study in pediatric patients.* This clinical trial, which was designed to evaluate the pharmacokinetics of single and multiple doses of Acetavance in 75 pediatric patients, demonstrated a pharmacokinetic profile for Acetavance generally comparable to adults, with an age-related reduction in clearance in newborns. Acetavance was well-tolerated across all age groups, ranging from newborns to adolescents.
- *Cadence Study 352, a safety study in pediatric patients.* This clinical trial is an open-label, multi-center, multi-day study to assess the safety in children of repeated doses of up to 15 mg/kg of Acetavance over at least five days. We completed enrollment in this trial in December 2008.

Other Clinical Trials Supporting Efficacy and Safety

In addition to the clinical trials required to be included in our NDA submission for Acetavance, we also plan to submit or reference other clinical trials and studies as part of our NDA, including:

- *Cadence Study 304, a Phase III clinical trial in adult patients with moderate pain following abdominal laparoscopic surgery.* This trial was a randomized, placebo-controlled, double-blind, multi-center study of 244 patients conducted by Cadence to assess the efficacy and safety of two dosing regimens of Acetavance, 1000mg administered every six hours and 650mg administered every four hours, compared to placebo over a 24-hour period. In December 2008, we announced that this study successfully met its primary endpoint of a statistically significant reduction in summed pain intensity differences from baseline over 24 hours, or SPID24, for Acetavance 1000mg compared to placebo ($p < 0.01$). The trial also achieved a statistically significant reduction in SPID24 for the 650mg dose administered every four hours ($p = 0.02$). Consistent with other placebo-controlled clinical trials with intravenous acetaminophen, the number of safety events reported for the group of patients who received Acetavance was similar to the number reported for the placebo treatment group.

- *Cadence Study 303, a Phase III clinical trial in adults with experimentally-induced fever versus oral acetaminophen.* This trial was a randomized, controlled, double-blind, double-dummy study of 81 subjects conducted by Cadence to assess the onset of action of a single dose of Acetavance compared to oral acetaminophen. In May 2008, we announced that a statistically significant difference in favor of Acetavance was observed compared to oral acetaminophen for the primary efficacy endpoint of the weighted sum of temperature differences over two hours ($p < 0.01$). The mean temperature scores for patients in the Acetavance treatment group were significantly lower as early as 15 minutes after the study drug was administered. The peak temperature observed in the Acetavance group was also significantly lower, and no treatment-emergent serious adverse events or treatment-emergent hepatic adverse events were reported for the Acetavance treatment group.
- *Moller, et al., a clinical trial in adults following oral surgery.* This study was a randomized, controlled, double-blind, parallel group trial in a total of 152 patients with moderate-to-severe pain after third molar surgery, comparing the analgesic efficacy of intravenous acetaminophen, propacetamol, which is a pro-drug that is rapidly converted in the bloodstream to acetaminophen, and placebo. The study demonstrated that six-hour weighted sums of primary assessments were significantly improved for the intravenous acetaminophen treatment group compared to the placebo group ($p < 0.0001$).
- *Cattabriga, et al., a clinical trial in adults following cardiac surgery.* This single center, placebo-controlled, double-blind, randomized trial in 113 patients examined the efficacy of intravenous acetaminophen as an adjunct to a tramadol-based background analgesia after cardiac surgery. The study demonstrated that at 12, 18 and 24 hours after surgery, patients who received intravenous acetaminophen had significantly less pain at rest ($p = 0.0041, 0.0039, \text{ and } 0.0044$, respectively). In addition, the intravenous acetaminophen group required less cumulative morphine than the placebo group (48mg vs. 97mg) although the difference was not statistically significant.
- *Atef, et al., a clinical trial in adults following elective tonsillectomy.* This study, which was a prospective placebo-controlled trial of intravenous acetaminophen in 76 adult patients following elective standard tonsillectomy procedures, demonstrated that intravenous acetaminophen was a rapid, effective and well tolerated analgesic in this moderate to severe postoperative pain setting. In addition to demonstrating improved pain relief, intravenous acetaminophen also significantly reduced opioid consumption over the 24-hour period. Over 70% of the patients in the intravenous acetaminophen group did not require opiate rescue medication in the 24-hour period after surgery. There were no significant differences in the number of adverse events reported for the intravenous acetaminophen and placebo treatment groups.
- *Kemppainen, et al., a clinical trial in adults following sinus surgery.* This prospective, double-blind, placebo-controlled clinical trial evaluated the efficacy and safety of intravenous acetaminophen in 74 patients undergoing endoscopic sinus surgery. The trial demonstrated that significantly fewer patients in the acetaminophen group required rescue analgesia ($p = 0.001$) and there was no significant difference between the groups in the incidence of adverse events.
- *BMS Study 136-01-03, a Phase III clinical trial in adults undergoing elective total hip arthroplasty.* This trial was a multi-center, randomized, double-blind, placebo-controlled study of 69 patients to assess the safety and efficacy of a single dose of intravenous acetaminophen compared to placebo. Although terminated prematurely due to the presence of particulates in the placebo material used in this study, at all primary time points assessed through four hours following the administration of intravenous acetaminophen, mean pain intensity differences, or PID, for the intravenous acetaminophen group was statistically significantly higher than for the placebo group ($p < 0.001$), indicating a greater reduction in pain intensity for the group of patients who received intravenous acetaminophen. In addition, the differences in PID between the treatment groups were statistically significant at all time points assessed through five hours ($p \leq 0.006$).
- *BMS Study 136-02-03, a Phase III clinical trial in adults undergoing elective total hip arthroplasty.* This trial was a multi-center, randomized, double-blind, placebo-controlled study of 61 patients to

assess the safety and efficacy of multiple doses of intravenous acetaminophen compared to placebo. While this study was terminated prematurely due to particulates in the placebo material used, at all primary time points assessed through four hours following dosing, the mean PID for the intravenous acetaminophen group was higher than for the placebo group, indicating a greater reduction in pain intensity for the group of patients who received intravenous acetaminophen. These differences were also statistically significant at all time points from 30 minutes through three hours after dosing ($p \leq 0.035$).

- *BMS Study 136-03-03, a Phase III clinical trial in adult females undergoing elective vaginal hysterectomy.* This trial was a multi-center, randomized, double-blind, placebo-controlled study of 44 patients to assess the safety and efficacy of multiple doses of intravenous acetaminophen compared to placebo. Although this study was terminated prematurely due to particulates in the placebo material used, at all primary time points assessed through four hours following dosing, mean PID for the intravenous acetaminophen group was higher than for the placebo group, indicating a greater reduction in pain intensity for the group of patients who received intravenous acetaminophen. The differences were also statistically significant at all time points from 30 minutes through three hours after dosing ($p \leq 0.035$).

OMIGARD™

Omigard was developed by researchers at Migenix. Migenix subsequently entered into a collaboration and license agreement with Fujisawa Healthcare, Inc., or Fujisawa, which is now known as Astellas Pharma, Inc. In January 2004, Migenix reacquired all rights to Omigard after the completion of the first Phase III clinical trial of this product candidate and in July 2004, licensed both the North American and European rights to us.

In June 2005, we reached agreement on our clinical development plan for Omigard with the FDA under the FDA's special protocol assessment, or SPA, process. Through the SPA process, the FDA agreed that a single Phase III clinical trial would be required for approval of Omigard, with the incidence of local catheter site infection, or LCSIs, as the primary efficacy endpoint.

On March 12, 2009, we announced results from our Phase III clinical trial of Omigard. This study, which is referred to as the Central Line Infection Reduction Study, or CLIRS trial, was a multinational, randomized, double-blind, active comparator-controlled Phase III trial designed to evaluate the safety and efficacy of Omigard compared to 10% povidone iodine in patients undergoing short term, non-cuffed central venous catheterization. A total of 1,859 patients were enrolled at 58 clinical trial sites in the United States and Europe. The primary efficacy endpoint of CLIRS was the incidence of LCSIs prior to study discharge among survivors in the modified intent to treat population for Omigard compared to 10% povidone-iodine. A determination of LCSIs was made by blinded evaluation committee adjudication. The study did not meet its primary endpoint, with an incidence of LCSIs of 6.3% for patients treated with Omigard compared to 8.6% for patients treated with povidone-iodine, which was not statistically significant (p -value=0.08). There was evidence of antimicrobial efficacy observed in two of the secondary endpoints. Microbiologically-confirmed LCSIs, the subset of patients with LCSIs plus a positive culture from the skin site or the catheter was 3.9% for patients treated with Omigard compared to 7.6% for patients treated with povidone-iodine ($p < 0.01$). For the endpoint of catheter colonization, which was a positive culture from the catheter, the incidence was 43.7% for patients treated with Omigard compared to 55.1% for patients treated with povidone-iodine ($p < 0.01$). For the secondary endpoint of catheter-related bloodstream infections, which was defined as matched cultures from both the catheter and the blood, the incidence was 19.5% for patients treated with Omigard compared to 23% for patients treated with povidone-iodine ($p = 0.08$). Safety data from CLIRS demonstrated that Omigard was generally safe and well tolerated. There were no statistically significant differences between Omigard and povidone-iodine across all key safety endpoints.

Although a positive trend was observed in the CLIRS trial, the study did not meet its primary objective, which was to demonstrate the superiority of Omigard compared to povidone-iodine for the prevention of LCSIs.

As a result, we made the strategic decision to discontinue further development of Omigard, implement cost reduction measures and restructure our operations to make additional resources available for our Acetavance program and other operating activities.

Our Commercialization Strategy

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

For the launch of Acetavance in the U.S., we intend to build our own commercial organization and estimate that a sales force of approximately 150-200 people will reach the top 1,800 to 2,000 U.S. hospitals, which we believe represents more than 80% of the market opportunity for this product candidate.

The primary target audience for Acetavance will include anesthesiologists and surgeons. Other targets will include certified registered nurse anesthetists, emergency medicine physicians, obstetricians and other physicians throughout the hospital.

The U.S. Hospital Market

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

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

Despite these declining promotional expenditures, U.S. hospitals and clinics accounted for approximately \$54 billion or 21% of U.S. pharmaceutical sales in 2005, according to IMS. Furthermore, we believe pharmaceutical sales to acute care hospitals are highly concentrated among a relatively small number of large institutions. For example, according to Wolters Kluwer Health, an independent marketing research firm, 2,000 of the approximately 5,000 acute care hospitals in the U.S. represent more than 80% of 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 waiting 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.

In addition to hospitals, we intend to promote our products to certain ambulatory care centers, including ambulatory surgery centers and dialysis clinics, which tend to be located in close proximity to a hospital and can be targeted with our hospital sales force. According to Verispan, there are approximately 5,000 outpatient surgery centers in the U.S. We estimate that fewer than 500 of these surgery centers represent the high opportunity segment for our products. According to the U.S. General Accounting Office, there are approximately 4,000 dialysis clinics in the U.S., of which we believe most are either co-located with a hospital or located in close proximity to a hospital.

Licensing Agreements

Acetavance

In March 2006, we in-licensed from BMS the patents and the exclusive development and commercialization rights to Acetavance 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 may be required to make future milestone payments totaling up to \$40.0 million upon the achievement of various milestones related to regulatory and commercial events. We are also obligated to pay a royalty on net sales of the licensed products. We have the right to grant sublicenses to our affiliates.

The term of the Acetavance agreement generally extends on a country-by-country basis until the last licensed patent expires, which is expected to occur in 2022. Either party may terminate the Acetavance 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 Acetavance agreement if we breach, in our capacity as a sublicensee, any provision of the agreement between BMS and Pharmatop. The Acetavance agreement will automatically terminate in the event of a termination of the license agreement between BMS and Pharmatop. We may terminate the Acetavance 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 Acetavance 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.

Omigard

In July 2004, we in-licensed from Migenix the patents and the exclusive development and commercialization rights to omiganan pentahydrochloride for the prevention and treatment of device-related, surgical wound-related and burn-related infections in North America and Europe.

As consideration for the license, we paid a \$2.0 million up-front fee, of which \$1.55 million was allocated to the value of the acquired technology and \$450,000 was attributed to the acquisition of 617,284 shares of Migenix common stock. We may be required to make future milestone payments totaling up to \$27.0 million upon the achievement of various milestones related to regulatory or commercial events. We are also obligated to pay a royalty on net sales of the licensed products. We have the right to grant sublicenses to third parties.

As a result of the discontinuation of our development program for Omigard, we are currently considering our options under our license agreement for this product candidate. The term of the Omigard agreement generally extends until the last licensed patent expires, which is expected to occur in November 2022. Either party may terminate the Omigard agreement upon specified written notice after the other party commits a material breach of its obligations and fails to remedy the breach or upon the cessation of operations of the other party or occurrence of specified bankruptcy, reorganization, liquidation or receivership proceedings involving the other party. We may terminate the Omigard agreement upon written notice if we determine, prior to regulatory approval in the U.S., that the product is not reasonably expected to demonstrate safety or efficacy. We may also terminate the Omigard agreement upon specified written notice after receipt of any interim results or the executive summary following database lock of our Phase III clinical trial for Omigard.

Intellectual Property

Acetavance

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 Acetavance and expires in August 2017. U.S. Patent No. 6,992,218 (Canadian patent application 2,415,403) covers the process used to manufacture Acetavance and expires in June 2021.

We have also in-licensed the non-exclusive rights to two U.S. patents from BMS. U.S. Patent No. 6,593,331 covers a method of treating pain with acetaminophen and concurrent administration of a hydroxyzapirone and expires in April 2022. US Patent No. 6,511,982 covers a method of treating pain with acetaminophen and concurrent administration of buspirone and expires in June 2020.

Omigard

We are the exclusive licensee of four U.S. patents, various pending U.S. applications, and their international equivalents in North America and Europe for the prevention and treatment of device-related, surgical wound-related, and burn-related infections with omiganan pentahydrochloride. U.S. Patent No. 6,180,604 and U.S. Patent No. 6,538,106 cover composition of matter for certain analogues of indolicidin, including Omigard, and expire in August 2017. U.S. Patent No. 6,503,881 covers composition of matter for additional analogues of indolicidin (not including Omigard), pharmaceutical preparations of certain analogues of indolicidin, including Omigard, and methods of using the pharmaceutical preparations for treating microbial infections (including covering routes of administration). U.S. Patent No. 6,503,881 also expires in August 2017. U.S. Patent No. 6,835,536 covers specific pharmaceutical preparations of certain analogues of indolicidin, including Omigard, and methods of treatment by applying pharmaceutical preparations to a target site, including a target site where a medical device is inserted. U.S. Patent No. 6,835,536 expires in November 2022.

Manufacturing

Acetavance

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

Omigard

In December, 2008, we entered into a long term supply agreement and a license agreement with Solvay SA, or Solvay, related to the commercial supply of the API for Omigard. Pursuant to the terms of these agreements, we agreed that Solvay would serve as our primary supplier for omiganan and agreed to purchase a majority of our aggregate annual requirements of omiganan from Solvay throughout the term of the seven-year supply agreement. Additionally, we agreed to pay development fees to Solvay upon the completion of specified manufacturing development activities and studies relating to omiganan. As a result of the discontinuation of our development program for Omigard, we are currently considering our options under our supply and license agreements with Solvay. We would not be required to pay the development, license transfer or other fees called for under these agreements if we exercise our termination rights, and we believe that the expenses associated with such termination would be minimal.

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 Acetavance and other product candidates we may license or acquire.

Acetavance

Acetavance is being developed for the treatment of acute pain and fever. A wide variety of competitive products already address the market for treatment of pain and fever in hospitalized patients, including:

Injectable opioids

- morphine is the leading product for the treatment of acute post-operative pain, and is available generically from several manufacturers;
- DepoDur, is 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

- ketorolac, an injectable NSAID, is available generically from several manufacturers.

Product Candidates

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

Government Regulation

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

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

FDA Approval Process

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

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

Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The institutional review board, or IRB, generally must

approve the clinical trial design and patient informed consent at each clinical site and may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

The applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. According to the FDA, the median total approval time for standard applications for approval of new drug and biological products during 2006 was approximately 14 months. 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 not approvable 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.

Other Regulatory Requirements

We may also be subject to a number of post-approval regulatory requirements. If we seek to make certain changes to an approved product, such as promoting or labeling a product for a new indication, making certain manufacturing changes or product enhancements or adding labeling claims, we will need FDA review and approval before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been

approved. Securing FDA approval for new indications or product enhancements and, in some cases, for manufacturing and labeling claims, is generally a time-consuming and expensive process that may require us to conduct clinical trials under the FDA's IND regulations. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. In addition, it has been reported that the new presidential administration may be seeking to curb practices that could result in the extension of the term of patent protection for pharmaceuticals, which may include applications for new indications or product enhancements.

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

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

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

In addition, we and the manufacturers on which we rely for the manufacture of our products are subject to requirements that drugs be manufactured, packaged and labeled in conformity with current good manufacturing practice, or cGMP. To comply with cGMP 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 cGMP requirements.

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

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

Third-Party Reimbursement and Pricing Controls

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

In many foreign markets, including the countries in the European Union, 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 27, 2009, we had 55 full-time employees, consisting of clinical development, regulatory affairs, manufacturing and program management, administration, business development and marketing. We consider our relations with our employees to be good. In connection with the discontinuation of our Omigard development program in March 2009, we committed to a corporate restructuring, which may include a work force reduction, in order to reduce costs.

Item 1A. Risk Factors

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission.

In the near-term, the success of our business will depend on many factors, including the following risks:

- We are dependent on the success of our only product candidate, Acetavance, and upon our ability to obtain regulatory approval for, and successfully commercialize, this product candidate on a timely basis;*
- The clinical trial and other data we plan to submit in our applications for regulatory approval may not be adequate to support the safety and efficacy of Acetavance;*
- We rely on third parties to assist us with our regulatory submission and other important aspects of our product development program, and our ability to obtain regulatory approval and commercialize Acetavance may be delayed if their performance is substandard or delayed, which would increase our costs, and result in the loss of potential revenues;*
- Changes made in scaling-up or transferring the manufacturing processes for Acetavance may result in a lack of comparability between our commercial product and the material used in our clinical trials, which could delay regulatory approval of this product candidate, substantially increase our costs and result in the loss of potential revenues;*
- We rely on our contract manufacturer to complete pre-commercialization manufacturing development activities, comply with stringent regulatory requirements and, if Acetavance is approved and commercialized, to produce Acetavance in the volumes that we require, and if our contract manufacturer fails to perform adequately or on a timely basis, our costs would be substantially increased and we may lose potential revenues;*
- Acetavance may be found to have undesirable side effects that could delay or prevent its regulatory approval or commercialization;*
- Recent publicity concerning the safety of certain drug products has resulted in heightened scrutiny by the FDA in the process of approving new drugs, which could delay or limit regulatory approval of Acetavance;*
- We expect intense competition from existing products, as well as any new products that may emerge that provide different or better therapeutic alternatives for our targeted indications, which could diminish the commercial potential of Acetavance;*
- The patent rights that we have in-licensed covering Acetavance 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; and*
- We will require substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our commercialization efforts and result in the loss of substantial revenues.*

Each of these factors, as well as other factors that may impact our business, are described in more detail in the following discussion. Although the factors highlighted above are among the most significant, any of the following factors could materially adversely affect our business or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time, and you should consider all of the factors described when evaluating our business.

Risks Related to Our Business and Industry

We are largely dependent on the success of our only product candidate, Acetavance, and we cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.

We currently have no drug products for sale and cannot guarantee that we will ever have marketable drug products. We currently have only one product candidate under development, and our business success depends on its successful development and commercialization. Any significant delay or failure to obtain the required regulatory approval for Acetavance would have a material adverse effect on our business and financial condition. For example, since obtaining the North American and European rights to Omigard, we devoted substantial effort and financial resources towards the completion of our development program for this product candidate, including approximately \$55.8 million in research and development expenses for the period of May 2004 through December 31, 2008, plus additional marketing costs, salaries and related personnel costs. In March 2009, we announced that we were discontinuing any further development of Omigard due to the failure of our Phase III clinical trial to meet its primary endpoint, and our belief that the results of this clinical trial would not support an NDA submission. As a result, we also announced that we were implementing cost reduction measures and restructuring our operations, including an anticipated workforce reduction, and that we would incur impairment charges in the fourth quarter of 2008 of approximately \$2.4 million on our manufacturing equipment for Omigard.

We have not submitted a new drug approval application, or NDA, to the FDA or received marketing approval for Acetavance. Any failure or significant delay in obtaining approval of our product candidate may prevent or delay our efforts to commercialize and derive revenues from our product candidate, and have a substantial adverse impact on our business.

We may not receive regulatory approval for Acetavance, or its approval may be delayed.

The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources. We currently plan to submit an NDA for Acetavance in the second quarter of 2009. As a company, we have no experience in filing and pursuing applications necessary to gain regulatory approvals, which may delay or impede our ability to obtain such approvals. Once our NDA has been submitted, the FDA may request additional information prior to accepting the submission for filing. Any delay in the acceptance of the NDA for Acetavance will result in a delay in receiving regulatory approval, and in our ability to derive revenues from sales of this product candidate, if approved.

If our NDA is accepted for filing, the FDA will begin an in-depth review of the submissions to determine whether to approve Acetavance for commercial marketing for the indications we have proposed. If the FDA is not satisfied with the information we provide, the agency may refuse to approve our NDA or may require us to perform additional nonclinical or clinical studies or provide other information in order to secure approval. The FDA may delay, limit or refuse to approve our NDA for many reasons, including:

- the information we submit may be insufficient to demonstrate that Acetavance is safe and effective;
- the FDA's interpretation of nonclinical, clinical, manufacturing or, pharmacovigilance data from use of this product candidate outside of the U.S., may differ from our own interpretation of such data;
- the FDA may determine that the clinical trials of Acetavance that were submitted in support of our NDA were not conducted in full compliance with the applicable protocols for these studies, as well as with applicable regulations and standards; or
- the FDA might not approve the processes or facilities that will be used for the commercial manufacture of Acetavance, if approved.

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

While the Prescription Drug User Fee Act of 1992, or PDUFA, specifies that the FDA has 10 months from acceptance to complete its initial review of a standard NDA, the review process may be extended by three months or longer if the FDA requests or we elect to provide additional information. For example, according to the FDA, the median total approval time for standard applications for approval of new drug and biological products during 2006 was approximately 14 months. There can be no assurance that regulatory approval will be obtained for Acetavance, and any failure or significant delay in obtaining the required approval would have a material adverse effect on our business and financial condition.

The clinical trial data we submit in our NDA for Acetavance may fail to adequately support its safety and efficacy, which could prevent or significantly delay its regulatory approval.

The data collected from clinical trials conducted by BMS that we plan to include in our NDA submission for Acetavance will be taken from databases that have been checked against original clinical study records that have been made available to us, but may not have been fully reconciled against medical records kept at the clinical sites. As a result of auditing and performing additional analyses of the data from the earlier clinical trials of this product candidate, the previously reported results, or the interpretation of those results, may change, which may negatively impact the suitability of such data for inclusion in applications for marketing authorization of Acetavance. As a result, we do not know whether the data will be adequate to support regulatory approval of Acetavance or any other product candidates that we may in-license or acquire. The rejection of data from any of the clinical trials required by regulatory authorities to support our NDA for Acetavance candidates could negatively impact our ability to obtain marketing authorization for this product candidate and have a material adverse effect on our business and financial condition.

All of the clinical trials that we intend to submit in our NDA for Acetavance to support the safety and efficacy of this product candidate in adults have been completed. We completed enrollment in the last required trial in our clinical development plan for Acetavance in children in December 2008. We currently plan to submit our NDA for this product candidate in the second quarter of 2009. We expect our NDA will include data from clinical trials of this product candidate performed by BMS in support of European regulatory approvals. Although the FDA has advised us that one of these studies, a clinical trial in patients undergoing total hip and knee replacement, may be submitted to demonstrate efficacy of Acetavance in the treatment of post-operative pain, the FDA may reject the results of this study if it determines that the study was not conducted in accordance with requisite regulatory standards and procedures. Furthermore, although we have audited or verified the accuracy of most of the primary clinical data provided by BMS for this study, as well as for other BMS studies, not all of the original medical records kept at the clinical sites have been made available to us. If the FDA does not agree with our interpretation of the results of clinical trials of Acetavance that we have conducted, or with our interpretation of the results of studies performed by BMS that we include in our NDA submission, our ability to obtain regulatory approval for this product candidate may be delayed, limited or otherwise adversely impacted. Our failure to obtain U.S. regulatory approval for Acetavance in a timely manner, or at all, will adversely affect our business and our stock price.

We rely on third parties to assist us with our clinical trials, regulatory submissions and other important aspects of our product development programs. If the performance of these third parties is substandard, or if they fail to successfully carry out their contractual duties or meet expected deadlines, the regulatory approval of our products may be delayed or prevented.

We have relied extensively upon independent clinical investigators, medical institutions, contract laboratories, contract research organizations, regulatory, statistical and other consultants, to perform important functions related to the conduct of our clinical trials, the collection and analysis of data, and the preparation of regulatory submissions for Acetavance. If the performance of any of these third parties is substandard, if they do not successfully carry out their contractual duties or meet expected deadlines, or if they are inspected by the FDA and are found not to be in compliance with our study protocols or with applicable regulations, including FDA guidelines for the conduct of clinical trials, the submission of our NDA for Acetavance may be delayed, or we may be prevented from obtaining regulatory approval for this product candidate.

If changes made in scaling-up or transferring the manufacturing processes for Acetavance result in a lack of comparability between our commercial product and the material used in our clinical trials, we may be required to perform additional non-clinical or clinical studies, which would delay the approval of our NDA for this product candidate, increase our costs and adversely affect our business.

We do not manufacture Acetavance, and do not currently plan to develop any capacity to do so. Instead, we rely on third-party manufacturers to manufacture and perform important pre-commercialization manufacturing development activities for this product candidate. As part of the process for obtaining regulatory approval, our contract manufacturers will need to demonstrate that the facilities, equipment and processes used to manufacture this product for potential commercial distribution are capable of consistently producing a product that meets all applicable quality criteria, and that is comparable to the product that was used in our clinical trials.

For example, although clinical trials were conducted using product manufactured by BMS, if Acetavance is approved, we plan to purchase this product from Baxter Healthcare Corporation, or Baxter, for commercial distribution. If the FDA determines that any of the changes we have made in scaling-up or transferring the manufacturing processes for Acetavance has resulted in a lack of comparability between the product used in our clinical trials and the product that will be manufactured for commercial distribution, we may be required to complete additional non-clinical studies or clinical trials in order to obtain regulatory approvals for Acetavance, which would increase our costs, result in the loss of potential revenues and adversely affect our business.

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

Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems may include unanticipated failures of production equipment, limited availability of critical materials, equipment and facilities, inadequate yields, shortages of qualified personnel, and quality control difficulties. In order to receive regulatory approval to commercialize this product candidate, we will need to provide the FDA with comprehensive information regarding the validation of the manufacturing facilities, equipment and processes of our third party manufacturers. Additionally, our contract manufacturer must produce specific batches of Acetavance that demonstrates acceptable stability under various conditions and for commercially viable lengths of time. The production of these batches requires complex, highly specialized equipment and materials, and involves the development of new processes and methods that may take a substantial amount of time to implement. Any delays in the availability of stability data, whether due to scheduling issues, equipment or process failures, materials shortages, or other reasons, may cause delays in the submission of applications for regulatory approval of Acetavance, and consequent delays in receiving FDA approval.

Additionally, the FDA will conduct inspections of our manufacturer's facilities from time to time, including as part of its review of our marketing application for Acetavance. If our manufacturer is not in compliance with cGMP requirements, the approval of our marketing application may be delayed, existing product batches may be recalled or otherwise compromised, and we may experience delays in the availability of this product candidate for commercial distribution.

If the third party manufacturer upon whom we rely fails to produce Acetavance in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of this product candidate or be unable to meet market demand, and may lose potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We have entered into a

development and supply agreement with Baxter for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of the finished Acetavance. Any termination or disruption of our relationships with Baxter may materially harm our business and financial condition, and frustrate any commercialization efforts for this product candidate. We are currently negotiating with suppliers for the commercial supply of the active pharmaceutical ingredient, or API, for Acetavance. If we need to change to another manufacturer or significantly change the manufacturing processes for this product candidate, we may be required to repeat or perform additional pre-clinical or clinical testing, which could increase our costs and cause delays in our ability to obtain regulatory approval. Additionally, we may not be able to establish or maintain commercial manufacturing arrangements on commercially reasonable terms for any other product candidates that we may in-license or acquire. If the commercial manufacturers upon whom we rely to manufacture Acetavance, and any other product candidates we may in-license, fail to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

All manufacturers of Acetavance and any other product candidates we may license or acquire must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program, and we have little control over our manufacturers' compliance with these regulations. The FDA and comparable international regulatory authorities must inspect and approve the facilities and processes of our contract manufacturers, and any delays in obtaining approval of our contract manufacturers could cause delays in the availability of our product candidates for commercial distribution. In addition, our contract manufacturers and their facilities will be subject to continual review and periodic inspections by the FDA. A 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.

Acetavance may have undesirable side effects that could delay or prevent its regulatory approval or commercialization.

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

For example, the adverse events observed in the Acetavance clinical trials completed to date include transient liver enzyme elevations, nausea or vomiting, allergic reactions, and pain or local skin reactions at the injection site. When used in excess of the current guidelines for administration, acetaminophen has an increased potential to cause liver toxicity. While the rate of adverse events in our clinical trials was comparable between the group of patients who received Acetavance and those who were in the placebo or control groups and, as a result, we do not expect the administration of acetaminophen in intravenous form will result in an increased risk of toxicity to the liver compared with an equivalent dose of acetaminophen administered orally, we cannot be certain that increased liver toxicity or other drug-related side effects will not be observed in future clinical trials, or as a result of sales of the same formulation of intravenous acetaminophen by BMS in Europe and other countries, or that the FDA will not require additional trials or impose more severe labeling restrictions due to liver toxicity or other concerns.

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

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

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

Even if Acetavance receives regulatory approval, it may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. If any such restrictions or requirements are imposed on Acetavance, our potential revenues from this product candidate could be adversely affected. For example, the label ultimately approved for Acetavance or any other product candidate that we may license or acquire, if any, may include restrictions on how such products may be used, and may not include one or more of our intended indications.

Acetavance and any other product candidates we may license or acquire will also be subject to ongoing FDA requirements with respect to the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If Acetavance or any other product candidates we may license or acquire fail to comply with applicable regulatory requirements, such as current Good Manufacturing Practices, or cGMPs, a regulatory agency may:

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

Even if Acetavance receives regulatory approval in the U.S., we may never receive approval or commercialize it outside of the U.S.

Our rights to Acetavance are limited to the U.S. and Canada. In order to market any products outside of the U.S., we must comply with numerous and varying regulatory requirements of other countries regarding

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

Recent publicity concerning the safety of certain drug products has resulted in heightened scrutiny by the FDA in the process of approving new drugs, which could delay or limit any regulatory approvals we may obtain for Acetavance.

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 establishment of risk management programs that may, for instance, restrict distribution of drug products after approval. In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving Acetavance, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of Acetavance, the indications for which this product candidate is approved may be limited, and our efforts to commercialize Acetavance may be otherwise adversely impacted.

We expect intense competition in the territories in which we have rights to Acetavance, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of Acetavance from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render Acetavance 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 Acetavance obsolete or noncompetitive.

We intend to seek marketing authorization for Acetavance for the treatment of acute pain and fever in adults and children, which will compete with well-established products for this and similar indications. Competing products available for the treatment of pain include opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are

available as proprietary products using novel delivery systems. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the U.S. from several manufacturers. 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. During the time that it will take us to obtain regulatory approval for Acetavance, if at all, we anticipate that several additional products may be developed for the treatment of acute pain, including other 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 and NSAIDs.

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

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

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

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

The commercial success of Acetavance will depend upon its acceptance by the medical community and coverage and reimbursement for Acetavance by third-party payors, including government payors. The degree of market acceptance of Acetavance or any other product candidate we may license or acquire will depend on a number of factors, including:

- limitations or warnings contained in a product's FDA-approved labeling, including potential limitations or warnings for Acetavance that may be more restrictive than oral formulations of acetaminophen;
- changes in the standard of care for the targeted indications for Acetavance could reduce the marketing impact of any superiority claims that we could make following FDA approval;
- limitations inherent in the approved indication for Acetavance compared to more commonly-understood or addressed conditions; and
- potential advantages over, and availability of, alternative treatments, including, in the case of Acetavance, a number of products already used to treat acute pain in the hospital setting.

Our ability to effectively promote and sell Acetavance and any other product candidates we may license or acquire in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to

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

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

In the U.S., we plan to build our own sales force to market Acetavance directly to physicians, nurses, hospitals, group purchasing organizations and third-party payors. The acquisition or development of a hospital-focused sales, marketing and distribution infrastructure for our domestic operations will be expensive and time consuming and, if not completed on time, could delay the launch of any approved products and otherwise negatively impact our commercialization efforts. Also, because we plan to begin hiring key sales and marketing personnel and implementing other pre-commercialization activities prior to the date on which we know whether or not Acetavance will be approved, we will incur significant commercialization costs for this product candidate before we know when or if it will be approved. Moreover, we may not be able to hire a sales force that is sufficient in size or has adequate expertise. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate any product revenue, may experience increased expenses, and may never become profitable.

We will need to obtain FDA approval of our proposed product name, Acetavance, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for Acetavance will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA typically conducts a rigorous review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims. If the FDA objects to the product name, Acetavance, we may be required to adopt an alternative name for this product candidate. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for Acetavance and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If the FDA delays approval of the proposed product name we may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize this product candidate.

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

In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. In particular, many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to our product candidates.

Accordingly, Acetavance 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. For example, in December 2003, Congress enacted a limited prescription drug benefit for Medicare beneficiaries in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Under this program, drug prices for certain prescription drugs are negotiated by drug plans, with the goal to lower costs for Medicare beneficiaries. In some foreign markets, 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. Such legislation could result in the exclusion of Acetavance and any other product candidates we may license or acquire from coverage and reimbursement programs, or lower the prices we would receive for our product candidates. Our revenues from the sale of any approved products could be significantly reduced as a result of these cost containment measures and reforms, which would negatively impact our profitability.

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

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

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

Our license for Acetavance 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 Acetavance. 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 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 indirectly in our loss of exclusive rights to our Acetavance product candidate and may lead to a complete termination of our product development and any commercialization efforts for Acetavance.

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

As of February 27, 2009, we had 55 full-time employees. We will need to continue to expand our managerial, operational, financial and other resources in order to manage and fund our operations and

development activities, prepare for the commercialization of Acetavance, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage the activities associated with the collection, review and analysis of data from our clinical trial programs for Acetavance;
- manage the substantial additional resources that are required to prepare and successfully file an NDA for Acetavance during the second quarter of 2009, including a significant number of consultants, CROs and other service providers;
- ensure that our consultants, CROs 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;
- prepare to hire, train and deploy an effective commercial organization in anticipation of the potential approval of Acetavance, and to establish appropriate systems, policies and infrastructure to support that organization; 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 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, and William R. LaRue, our Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary. 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 and Mr. LaRue, 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 Acetavance or other product candidates we may license or acquire and may have to limit their commercialization.

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

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

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

Proposed legislation may permit re-importation of drugs from foreign countries into the U.S., including foreign countries where the drugs are sold at lower prices than in the U.S., which could materially adversely affect our operating results and our overall financial condition.

Legislation has been introduced in Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the U.S., which may include re-importation from foreign countries where the drugs are sold at lower prices than in the U.S. Such legislation, or similar regulatory changes, could decrease the price we receive for any approved products which, in turn, could materially adversely affect our operating results and our overall financial condition. For example, BMS markets Acetavance in Europe and other countries principally under the brand name Perfalgan. Although Perfalgan is not labeled for sale in the U.S. and we have an exclusive license from BMS and its licensor to develop and sell Acetavance in the U.S., it is possible that hospitals and other users may in the future seek to import Perfalgan rather than purchase Acetavance in the U.S. for cost-savings or other reasons. We would not receive any revenues from the importation and sale of Perfalgan into the U.S.

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

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

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

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

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

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

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

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for Acetavance could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or

security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidate may be delayed.

Risks Related to Intellectual Property

The patent rights that we have in-licensed covering Acetavance 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 Acetavance 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 Acetavance 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 Acetavance product candidate is found to infringe any of these method patents covering acetaminophen, our supply of the API could be delayed and we may be required to locate an alternative supplier. We are also aware of several U.S. and Canadian patents and patent applications covering various potential injectable formulations of acetaminophen as well as methods of making and using these potential formulations. For example, Injectapap, a liquid formulation of acetaminophen for intramuscular injection, was approved by the FDA for the reduction of fever in adults in March 1986, although it was subsequently withdrawn from the market by McNeil Pharmaceutical in July 1986.

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

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

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

Either BMS or SCR Pharmatop, depending on the patent or application, is responsible for maintaining issued patents and prosecuting patent applications. SCR Pharmatop is under a contractual obligation to BMS to diligently prosecute their patent applications and allow BMS the opportunity to consult, review and comment on patent office communications. However, we cannot be sure that SCR Pharmatop will perform as required. Should BMS decide it no longer wants to maintain any of the patents licensed to us, BMS is required to afford us the opportunity to do so at our expense. However, we cannot be sure that BMS will perform as required. If BMS does not perform, and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights. Moreover, either BMS or SCR Pharmatop may experience serious difficulties related to their overall business or financial stability, and they may be unwilling or unable to continue to expend the financial resources required to maintain and prosecute these patents and patent applications. While we intend to

take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors to protect a substantial portion of our proprietary rights. BMS has the first right to prosecute a third-party infringement of the SCR Pharmatop patents, and has the sole right to prosecute third-party infringement of the BMS patents. We will have the ability to cooperate with BMS in third-party infringement suits involving the SCR Pharmatop patents. It is possible that SCR Pharmatop or BMS could take some action or fail to take some action that could harm the SCR Pharmatop patents. In certain instances, we may be allowed to pursue the infringement claim ourselves.

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

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

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

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for Acetavance 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 Acetavance 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 Acetavance 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 Acetavance may infringe. There could also be existing patents of which we are not aware that Acetavance may inadvertently infringe.

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

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

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

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Finances and Capital Requirements

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

We are a development stage company with a limited operating history. We have focused primarily on in-licensing and developing Acetavance and our former product candidate, Omigard, 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 \$57.1 million, \$51.7 million and \$52.2 million for the years ended December 31, 2008, 2007 and 2006, respectively. As of December 31, 2008, we had an accumulated deficit of \$171.5 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect our development expenses to decrease over the next few years due to the significant completion of our clinical development program for Acetavance, and the discontinuation of our development program for Omigard. However, our expenses to support regulatory approval and product manufacturing are expected to increase in connection with activities required to prepare and submit an NDA for Acetavance during the first half of 2009. Further, we expect to incur increased pre-commercialization expenses during the second half of 2009 as we prepare for the market launch of Acetavance. In addition, if we obtain regulatory approval for Acetavance, we expect to incur significant sales, marketing and outsourced manufacturing expenses, as well as continued development expenses. As a result, we expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

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

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

- successfully complete our collection, review and analysis of data from our clinical trials of Acetavance in preparation for submitting an NDA for this product candidate;
- obtain regulatory approvals for Acetavance, or any other product candidates that we may license or acquire;
- manufacture commercial quantities of Acetavance, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell Acetavance, if it is approved.

Even if Acetavance is approved for commercial sale, we anticipate incurring significant costs associated with its commercialization. We also do not anticipate that we will achieve profitability for at least several years 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 Acetavance since March 2006 and our discontinued Omigard product candidate since July 2004. Our operations to date have been limited to organizing and staffing our company, in-licensing and conducting product development activities, including clinical trials and manufacturing development activities, for Acetavance and Omigard. We have not yet demonstrated an ability to obtain regulatory approval for or successfully commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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

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

- fund our operations and continue to collect, review and analyze clinical data from our clinical trials to support regulatory approval of marketing applications for Acetavance;
- continue our development activities;
- qualify and outsource the commercial-scale manufacturing of our products under cGMP; and
- commercialize Acetavance, if approved by regulatory authorities.

In February 2009, we completed a private placement of common stock and warrants to purchase common stock, raising aggregate gross proceeds of approximately \$86.6 million. We believe that with the proceeds of this financing, and our existing cash and cash equivalent balance as of December 31, 2008, we have sufficient funds to meet our projected operating requirements for, at a minimum, the next eighteen months. We have based this estimate on assumptions that may prove to be wrong and we could spend our available financial resources faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and costs of our efforts to prepare for the submission of an NDA for Acetavance and any other product candidates that we may in-license or acquire, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;

- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of completion of outsourced commercial manufacturing supplies for each product candidate;
- the costs and timing of regulatory approval;
- the costs of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and
- the success of the commercialization of our products.

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

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

Our quarterly operating results may fluctuate significantly.

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

- the timing of milestone payments required under our license agreement for Acetavance;
- our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- our addition, modification or termination of clinical trials or funding support;
- variations in the level of expenses related to Acetavance or future development programs;
- any product liability or intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting Acetavance or the product candidates of our competitors; and
- if Acetavance receives regulatory approval, the level of underlying hospital demand for this product candidate and wholesalers' buying patterns.

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

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

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

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

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

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

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

Our net operating loss carryforwards and research and development tax credits may expire and not be used. As of December 31, 2008, we have generated federal and state net operating loss carryforwards of approximately

\$131.9 million, and federal and state research and development tax credit carryforwards of approximately \$3.1 million and \$1.3 million, respectively. Our net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2014 for state purposes if we have not used them prior to that time, and our federal tax credits will begin expiring in 2024 unless previously used. Our state tax credits carryforward indefinitely. Additionally, our ability to use any net operating loss and credit carryforwards to offset taxable income in the future will be limited under Internal Revenue Code Sections 382 and 383 if we have a cumulative change in ownership of more than 50% within a three-year period. We have not completed an analysis as to whether such a change of ownership has occurred, but in such an event, may be limited to the amount of net operating loss carryforwards and research tax credits that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire.

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

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

Risks Relating to Securities Markets and Investment in Our Stock

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

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

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

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. For example, the volatility in the overall capital markets has reached unprecedented levels during 2008, which affected most equity securities. This 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 2008 ranged from a high of \$15.00 to a low of \$4.39. The market price of our common stock is likely to continue to be highly volatile and may fluctuate substantially due to many factors, including:

- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;

- price and volume fluctuations in the overall stock market;
- market reaction to the discontinuation of our development program for Omigard and related restructuring activities;
- FDA or international regulatory actions, including significant delays in receiving, or the failure to receive, regulatory approval for Acetavance;
- failure of Acetavance, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

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

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

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock that they may now be able to sell in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, the holders of a substantial number of shares of common stock may have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders. For example, we have agreed to register 18,059,691 shares of our common stock, including shares underlying warrants, in connection with a PIPE financing completed in February 2009. Once the registration statement covering these shares is declared effective by the SEC, all of these shares generally may be freely sold in the public market, subject to volume and other limitations applicable to our affiliates. We may be liable for liquidated damages to holders of the shares if the registration statement is not declared effective by May 19, 2009 (if it does not become subject to review by the SEC), or by June 18, 2009 (if it becomes subject to review by the SEC). The amount of the liquidated damages is 1% per month, subject to an aggregate cap of 8% per calendar year, of the aggregate purchase price of the shares (but not the warrant shares) then held by the purchasers that are registrable securities.

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, 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 February 27, 2009, our executive officers and directors and their affiliates together controlled approximately 51.2% of our outstanding common stock. As a result, these stockholders will collectively be able to significantly influence all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets, and might affect the prevailing market price of our common stock.

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

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

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations;
- a requirement of approval of not less than 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 amended loan and

security agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc. restricts our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

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

Item 1B. *Unresolved Staff Comments*

Not applicable.

Item 2. *Properties*

We lease approximately 23,494 square feet of space in our headquarters in San Diego, California under a sublease that expires in 2012, of which we occupy approximately 16,600 square feet. We have subleased the remainder through the third quarter of 2009. We have no laboratory, research or manufacturing facilities; however we do own manufacturing equipment which is located at our third-party contractors. We currently do not plan to purchase or lease facilities for manufacturing, packaging or warehousing, as such services are provided to us by third-party contractors. We believe that our current facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. *Legal Proceedings*

We are not engaged in any legal proceedings.

Item 4. *Submission of Matters to a Vote of Security Holders*

Not applicable.

PART II

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

Market Information

Our common stock has been traded on the NASDAQ Global Market since October 25, 2006 under the symbol "CADX." Prior to that time, there was no public market for our common stock. As of February 27, 2009, there were 50,403,779 shares of common stock outstanding held by approximately 50 stockholders of record. Many stockholders hold their shares in street name. We believe that there are more than 2,000 beneficial owners of our common stock. The closing price of our common stock on the NASDAQ Global Market on December 31, 2008 was \$7.23 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,			
	2008		2007	
	High	Low	High	Low
Period:				
First Quarter	\$15.00	\$4.84	\$16.92	\$11.70
Second Quarter	\$ 7.85	\$5.71	\$18.55	\$11.61
Third Quarter	\$12.01	\$6.00	\$15.24	\$11.57
Fourth Quarter	\$ 9.06	\$4.39	\$15.70	\$11.64

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2008, about our common stock that may be issued upon the exercise of stock options granted to employees, consultants and members of our board of directors under all existing equity compensation plans including our 2006 Equity Incentive Award Plan and our 2004 Equity Incentive Award Plan. The 2006 Equity Incentive Award Plan was adopted at the time of our initial public offering in October 2006 which coincided with the discontinuance of the 2004 Equity Incentive Award Plan. See Note 8 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, 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	3,629,430 ⁽¹⁾	\$6.33	1,236,515 ⁽²⁾
Equity compensation plans not approved by security holders	—	—	—
Total.	3,629,430	\$6.33	1,236,515 ⁽²⁾

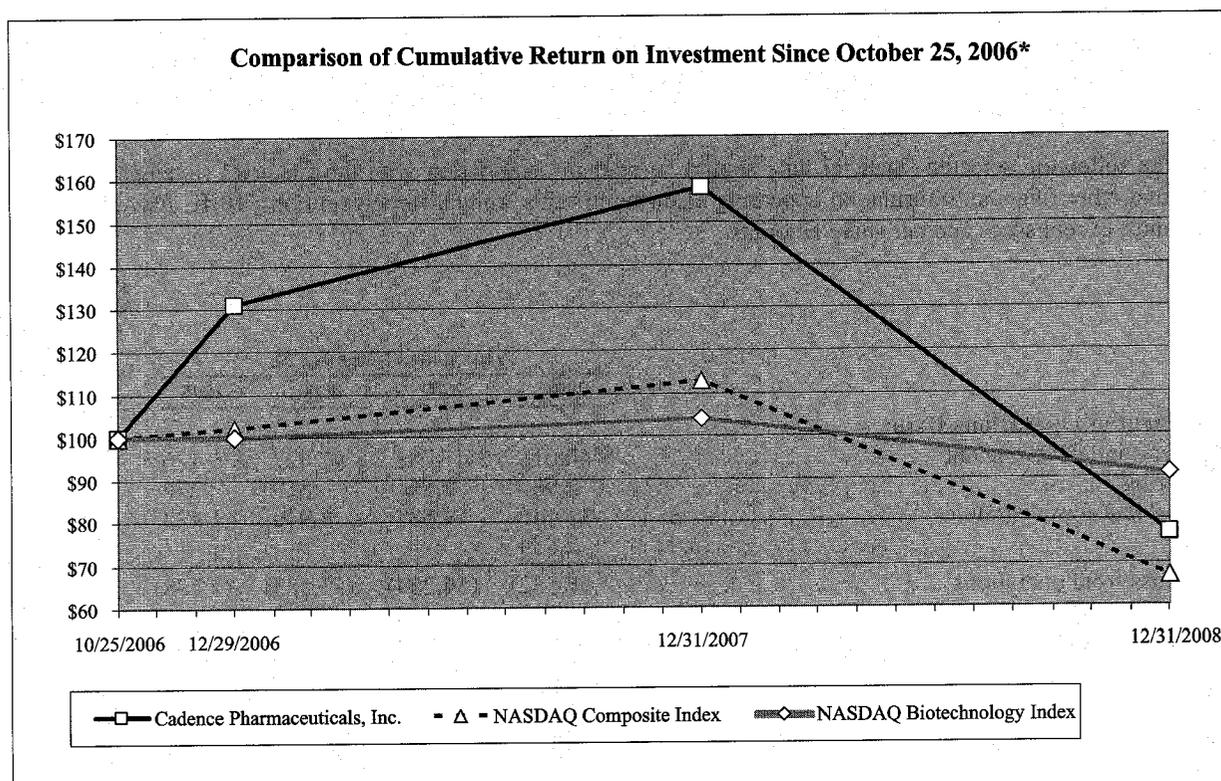
(1) Of these shares of Common stock, 2,046,250 shares were subject to outstanding options under the 2006 Equity Incentive Award Plan and 1,583,180 shares were subject to outstanding options under the 2004 Equity Incentive Award Plan.

(2) The 2006 Equity Incentive Award Plan contains an "evergreen" provision which allows for annual increases in the number of shares available for future issuance on January 1 of each year during the ten-year term of

the plan, beginning on January 1, 2008. The annual increase in the number of shares shall be equal to the lesser of (i) 4% of our outstanding common stock on the applicable January 1 or (ii) such lesser amount determined by our board of directors.

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>
Cadence Pharmaceuticals, Inc.	\$100	\$131	\$158	\$77
NASDAQ Composite Index	\$100	\$102	\$113	\$67
NASDAQ Biotechnology Index	\$100	\$100	\$104	\$91

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

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our common stock. We expect to retain future earnings, if any, to fund the development and growth of our business. The payment of dividends by us on our common stock is limited by our loan and security agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc. Any future determination to pay dividends on our common stock will be at the discretion of our

board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

Issuer Repurchases of Equity Securities

Not applicable.

Item 6. Selected Financial Data

The selected financial data set forth below is derived from our audited financial statements and may not be indicative of future operating results. Audited balance sheets at December 31, 2008 and 2007 and the related audited statements of operations and of cash flows for each of the three years in the period ended December 31, 2008 and notes thereto appear elsewhere in this Annual Report on Form 10-K. Audited balance sheets at December 31, 2006, 2005 and 2004 and the related audited statements of operations and of cash flows for 2005 and the period from May 26, 2004 (inception) through December 31, 2004 are not included elsewhere in this Annual Report on Form 10-K.

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

	Year Ended December 31,				Period from
	2008	2007	2006	2005	May 26, 2004 (Inception) Through December 31, 2004
Statement of Operations Data:					
Research and development	\$ 40,018	\$ 41,781	\$ 47,827	\$ 6,126	\$ 1,883
Marketing	2,984	2,866	810	240	41
General and administrative	11,146	9,587	4,946	1,412	877
Other	2,384	—	—	—	—
Loss from operations	(56,532)	(54,234)	(53,583)	(7,778)	(2,801)
Interest income	1,530	3,404	1,945	255	9
Interest expense	(1,916)	(867)	(498)	—	—
Other expense	(180)	(17)	(37)	(183)	(45)
Net loss	<u>\$(57,098)</u>	<u>\$(51,714)</u>	<u>\$(52,173)</u>	<u>\$(7,706)</u>	<u>\$(2,837)</u>
Basic and diluted net loss per share ⁽¹⁾	<u>\$ (1.55)</u>	<u>\$ (1.81)</u>	<u>\$ (10.07)</u>	<u>\$ (6.67)</u>	<u>\$ (3.10)</u>

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

	As of December 31,				
	2008	2007	2006	2005	2004
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	\$ 47,627	\$ 55,393	\$ 86,826	\$ 15,025	\$ 4,271
Working capital	28,385	36,839	76,203	14,405	4,161
Total assets	55,148	64,612	93,092	15,891	4,841
Long-term debt, less current portion and discount	6,098	13,412	4,433	—	—
Deficit accumulated during the development stage	(171,528)	(114,429)	(62,716)	(10,543)	(2,837)
Total stockholders' equity	26,440	28,458	75,409	14,745	4,727

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

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

Overview

Background

We are a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. We were incorporated in May 2004 and during that year we focused on hiring our management team and initial operating employees. Since that time, we have in-licensed rights to two late-stage product candidates, Acetavance™, a proprietary intravenous formulation of acetaminophen, and Omigard™, or omiganan pentahydrochloride 1% aqueous gel. Substantial operations did not commence until September 2004. During 2005, we completed the special protocol assessment, or SPA, for Omigard, and initiated Phase III clinical trials for this product candidate. In March 2006, we in-licensed rights to Acetavance 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 this product candidate for the treatment of acute pain and fever in adults and children. We believe that Acetavance may fulfill significant unmet needs in the hospital setting. We also believe that the hospital pharmaceuticals market is both concentrated and underserved which may enable us to build our own hospital-focused sales force as Acetavance approaches potential U.S. Food and Drug Administration, or FDA, approval. 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 December 2008, we announced that we had completed our clinical development program for Acetavance in adults. We completed enrollment in the last required trial in our clinical development plan for Acetavance in children in December 2008. We currently plan to submit an NDA to the FDA in the second quarter of 2009, requesting marketing approval of Acetavance for the treatment of acute pain and fever in adults and children.

We completed enrollment in our Phase III clinical trial of Omigard in April 2008. In March 2009, we announced that this clinical trial did not meet its primary objective, and that we were discontinuing our development efforts for Omigard because we believe that the results of this clinical trial would not support an NDA submission for this product candidate. At the same time, we announced that we were implementing cost reduction measures and restructuring our operations to make additional resources available for our Acetavance development program and other operating activities. We are a development stage company and we have incurred significant net losses since our inception. As of December 31, 2008, we had an accumulated deficit of \$171.5 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 current product candidates and general and administrative expenses. The discontinuation of our development program for Omigard in March 2009 resulted in impairment charges in the fourth quarter of 2008 of approximately \$2.4 million on our manufacturing equipment for this product candidate. We expect to continue to incur operating losses for the next several years as we pursue the clinical development and market launch of Acetavance and acquire or in-license additional products, technologies or businesses that are complementary to our own.

In October 2006, we completed an initial public offering in which we sold 6.0 million shares of our common stock at \$9.00 per share and received aggregate net proceeds of \$48.4 million (after underwriting discounts and

offering costs). In November 2006, following exercise of the underwriters' over-allotment option, we sold 0.9 million shares of our common stock at \$9.00 per share and received aggregate net proceeds of \$7.5 million (after underwriting discounts). In February 2008, we completed a registered direct offering pursuant to an effective shelf registration statement under which we issued and sold 9.2 million shares of common stock at \$5.34 per share and received aggregate net proceeds of approximately \$49.1 million (after offering costs). In February 2009, we raised additional funds by completing a private placement of approximately 12.0 million shares of common stock at a price of \$7.13 per share, and warrants to purchase up to approximately 6.0 million additional shares of common stock at a price of \$0.125 per warrant, for aggregate gross proceeds of approximately \$86.6 million. Each warrant has a five-year term and is exercisable in cash or by net exercise for one share of common stock at a price of \$7.84. The securities sold in the private placement have not been registered under the Securities Act of 1933, as amended, or any state securities laws, and were sold pursuant to Regulation D of the Securities Act. These securities may not be offered or sold in the U.S. absent registration or pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws, and we have agreed to file a registration statement no later than March 20, 2009 covering the resale of the shares of common stock acquired by the investors and shares of common stock issuable upon exercise of the warrants acquired by the investors.

Revenues

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

Research and Development Expenses

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

Our historical research and development expenses relate predominantly to Acetavance and our discontinued product candidate, Omigard. We expense all research and development charges as they are incurred as the underlying technology associated with these expenditures relates to our research and development efforts and has no alternative future uses. We use external service providers and vendors to conduct our clinical trials, to manufacture our product candidates to be used in clinical trials and to provide various other research and development related products and services. A substantial portion of these external costs are tracked on a project basis. 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.

The following table summarizes our research and development expenses included in our statements of operations by project for the periods indicated. Costs that are not attributable to a specific product candidate, including salaries and related personnel costs, are included in the "other supporting costs" category (in thousands):

	Year Ended December 31,			Period from May 26, 2004 (Inception) through December 31, 2008
	2008	2007	2006	
Acetavance ⁽¹⁾	\$15,234	\$14,107	\$28,052	\$ 57,393
Omigard ⁽²⁾⁽³⁾	14,809	20,191	14,343	55,796
Other supporting costs	9,975	7,483	5,432	24,447
	<u>\$40,018</u>	<u>\$41,781</u>	<u>\$47,827</u>	<u>\$137,636</u>

- (1) We paid an up-front license fee of \$25.0 million in 2006 for Acetavance, which is included in the costs for the year ended December 31, 2006 and for the period from May 26, 2004 (inception) through December 31, 2008. We may be required to make future milestone payments totaling up to \$40.0 million upon the achievement of various milestones related to regulatory and commercial events in addition to royalties on the sales of the licensed products.
- (2) We paid an up-front license fee of \$2.0 million in 2004 for Omigard, of which \$1.5 million is included in the costs for the period from May 26, 2004 (inception) through December 31, 2008. We may be required to make future milestone payments totaling up to \$27.0 million upon the achievement of various milestones related to regulatory or commercial events in addition to royalties on the sales of the licensed products.
- (3) For the fourth quarter of 2008, we recorded an impairment charge of \$2.4 million on our Omigard manufacturing equipment due to the discontinuation of our Omigard development program. This charge is presented separately on our statement of operations in Other Operating Expenses and is not included in the amount presented for the year ended December 31, 2008.

At this time, due to the risks inherent in the clinical trial and regulatory approval processes, we are unable to estimate with any certainty the costs we will incur in completing the development and obtaining approval from the FDA for the potential commercialization of Acetavance. Clinical development and regulatory approval timelines, the probability of success and development costs vary widely. We are currently focused on completing our product development program for Acetavance and obtaining marketing authorizations for this product candidate. We cannot forecast with any degree of certainty whether Acetavance will be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

We expect our development expenses to decrease over the next few years due to the significant completion of our existing clinical development program for Acetavance and the discontinuation of our development program for Omigard. We currently plan to submit an NDA to the FDA in the second quarter of 2009, requesting marketing approval of Acetavance for the treatment of acute pain and fever in adults and children.

Marketing Expenses

Our marketing expenses consist primarily of market research studies and pre-launch marketing activities, salaries, benefits and professional fees related to building our marketing capabilities. We anticipate substantial increases in marketing expenses as we continue to develop and prepare for the potential commercialization of Acetavance, including the addition of marketing and hospital-focused sales personnel to market our products to physicians, nurses, group purchasing organizations and third-party payors.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries, benefits and professional fees related to our administrative, finance, human resources, legal, business development and internal systems support functions, as well as insurance and facility costs. We anticipate increases in general and administrative expenses as we continue to build our corporate infrastructure in support of our continued development and preparation for the potential commercialization of Acetavance.

Interest and Other Income and Expense

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

Long-Lived Assets

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

For the fourth quarter of 2008, we recorded an impairment charge of \$2.4 million on our Omigard manufacturing equipment due to the discontinuation of our Omigard program. No similar impairments were recorded for 2007 or 2006.

Income Taxes

In July 2006, the Financial Accounting Standards Board, or FASB, issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—An Interpretation of FASB Statement No. 109*, or FIN No. 48. FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*, and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN No. 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN No. 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. We adopted the provisions of FIN No. 48 on January 1, 2007. On the date of adoption of FIN No. 48, there were no unrecognized tax benefits and thus we did not recognize an increase in the liability for unrecognized tax benefits. Further, there are no unrecognized tax benefits included in our balance sheet at December 31, 2008 and 2007, respectively.

As of December 31, 2008, we had both federal and state net operating loss carryforwards of approximately \$131.9 million. If not utilized, the net operating loss carryforwards will begin expiring in 2024 for federal

purposes and 2014 for state purposes. As of December 31, 2008, we had both federal and state research and development tax credit carryforwards of approximately \$3.1 million and \$1.3 million, respectively. The federal tax credits will begin expiring in 2024 unless previously utilized and the state tax credits carryforward indefinitely. Under Section 382/383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards and development tax credit carryforwards that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating losses and tax credits before they expire. We have not completed a Section 382/383 study at this time. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recognized any federal or state income tax benefit in our statement of operations.

Critical Accounting Policies and Estimates

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

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

Research and Development Expenses

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

Stock-Based Compensation

We account for stock-based compensation under the provisions of Statement of Financial Accounting Standards, or SFAS, No. 123(R), *Share-Based Payment*, which revises SFAS No. 123, *Accounting for Stock-Based Compensation* and supersedes Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*. Under SFAS No. 123(R), we calculate the fair value of our stock-based compensation

awards to our employees and directors using the Black-Scholes pricing model. This model requires a number of estimates to be used in determining the fair value, including the expected lives of awards, interest rates, stock volatility and other assumptions. A change in any of the estimates used in the model, or the selection of a different option pricing model, could have a material impact on our operations. Equity instruments issued to non-employees are recorded at their fair value as determined in accordance with SFAS No. 123(R) and Emerging Issues Task Force 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period. For further discussion regarding the implementation of SFAS No. 123(R), see Note 2 of the Notes to Financial Statements in Item 8 of this Annual Report on Form 10-K.

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

	Year Ended December 31,			Period from
	2008	2007	2006	May 26, 2004 (Inception) through December 31, 2008
Research and development	\$1,967	\$1,243	\$ 561	\$ 3,771
Marketing	61	33	1	95
General and administrative	3,910	3,064	1,573	8,547
Stock-based compensation expense included in operating expenses	5,938	4,340	2,135	12,413
Total stock-based compensation expense included in loss from operations	<u>\$5,938</u>	<u>\$4,340</u>	<u>\$2,135</u>	<u>\$12,413</u>

Results of Operations

Years ended December 31, 2008 and 2007

Operating Expenses

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

- a decrease of \$5.4 million in spending for our Omigard development program, primarily due to a reduction in clinical trial activity as enrollment was completed in our CLIRS trial in April 2008, partially offset by an increase in pre-commercialization manufacturing development activities;
- an increase of \$2.5 million in other supporting costs (including \$0.7 million of additional stock-based compensation charges), primarily related to additional salary and related personnel costs resulting from the increase in research and development staff employed during 2008 as compared to 2007, combined with severance costs associated with the departure of an officer during the third quarter of 2008; and
- an increase of \$1.1 million in research and development expenses for Acetavance, primarily as a result of increased clinical trial activity during 2008 as compared to 2007, combined with increased costs related to preparations for our NDA filing, which is expected to occur in the second quarter of 2009. The increase in costs for this program was partially offset by facility improvement charges at our manufacturing site incurred primarily in 2007.

We expect our development expenses to decrease over the next few years due to the significant completion of our existing clinical development programs.

Marketing Expenses. Marketing expenses increased \$0.1 million in 2008 to \$3.0 million, compared to \$2.9 million for 2007. This slight increase was primarily due to increased salaries and related personnel costs from the addition of marketing staff in 2008 as compared to 2007. We anticipate substantial increases in marketing expenses in the future as we continue to prepare for the potential commercialization of Acetavance.

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

Other Operating Expenses. For the fourth quarter of 2008, we recorded an impairment charge of \$2.4 million on our Omigard manufacturing equipment due to the discontinuation of our Omigard development program. There were no similar charges during 2007.

Other Income and Expenses, Net

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

Years ended December 31, 2007 and 2006

Operating Expenses

Research and Development Expenses. Research and development expenses decreased \$6.0 million in 2007 to \$41.8 million, compared to \$47.8 million for 2006. This decrease was primarily due to the \$25.3 million initial license fee and related costs for Acetavance, which we incurred in March 2006, and was immediately expensed as in-process research and development. Excluding this license fee and related costs, our research and development expenses for 2007 increased \$19.3 million. This increase in 2007 as compared to 2006 was primarily due to the advancement of our clinical development programs for Acetavance, which was initiated in October 2006, and Omigard, which was initiated in August 2005. More specifically, the increases were as follows:

- an increase of \$11.4 million in our Acetavance program, primarily as a result of costs related to the progress of our Phase III clinical trials and pre-commercialization manufacturing development activities;
- an increase of \$5.8 million in our Omigard program as a result of costs related to our Phase III clinical trial of this product candidate due to higher enrollment rates and pre-commercialization manufacturing development activities; and
- an increase of \$2.1 million in other supporting costs as a result of increased salaries and related personnel costs from the addition of research and development staff hired to support our clinical and regulatory efforts related to both Omigard and Acetavance. This increase includes \$0.7 million of additional stock-based compensation charges in 2007 as compared to 2006.

Marketing Expenses. Marketing expenses increased \$2.1 million in 2007 to \$2.9 million, compared to \$0.8 million for 2006. This increase was primarily due to increased market research and related costs for Acetavance and Omigard and increased salaries and related personnel costs from the addition of marketing staff in 2007 as compared to 2006.

General and Administrative Expenses. General and administrative expenses increased \$4.7 million in 2007 to \$9.6 million, compared to \$4.9 million for 2006. This increase was primarily due to increases in salaries and related personnel costs (including an increase of \$1.5 million in stock-based compensation charges) from the addition of general and administrative staff in 2007 as compared to 2006, costs related to operating as a public company, fees paid to our board of directors and depreciation expense, partially offset by a decline in net rent expense.

Other Income and Expenses, Net

Interest income increased \$1.5 million in 2007 to \$3.4 million, compared to \$1.9 million for 2006. This increase was primarily due to our increased average cash and cash equivalents balance in 2007 as a result of the proceeds we received from the completion of our initial public offering in the fourth quarter of 2006. Additionally, our investments benefited from higher average interest rates in 2007 as compared to 2006. Interest expense increased \$0.4 million in 2007 to \$0.9 million, compared to \$0.5 million for 2006. This increase was primarily due to the additional interest we incurred during 2007 on the outstanding balance of our \$7.0 million credit facility drawn down in June 2006.

Liquidity and Capital Resources

As a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary pharmaceutical product candidates, we have entered into license agreements to acquire the rights to develop and commercialize our two product candidates, Acetavance and Omigard. Pursuant to these agreements, we obtained exclusive licenses to the patent rights and know-how for selected indications and territories. Under the Acetavance agreement, we paid to BMS a \$25.0 million up-front fee and may be required to make future milestone payments totaling up to \$40.0 million upon the achievement of various milestones related to regulatory and commercial events. Under the Omigard agreement, 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, and may be required to make future milestone payments totaling up to \$27.0 million upon the achievement of various milestones related to regulatory or commercial events. Under both agreements, we are also obligated to pay royalties on any net sales of the licensed products. As a result of the discontinuation of our development program for Omigard, we are evaluating our options under the license agreement for this product candidate.

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

- the rate of progress and costs of our efforts to prepare for the submission of an NDA for Acetavance and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Acetavance and any other product candidate we may license or acquire, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the costs and timing of securing sufficient supplies of Acetavance from our contract manufacturers in preparation for commercialization;
- the costs and timing of regulatory approval;
- the costs of establishing sales, marketing and distribution capabilities;

- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and
- the success of the commercialization of our products.

As of December 31, 2008, we had \$47.6 million in cash and cash equivalents, a decrease of \$7.8 million from the \$55.4 million at December 31, 2007. This decrease was primarily due to the cash used in operations (\$49.7 million), principal payments on our debt obligations (\$5.6 million) and the purchase of equipment (\$1.7 million) during the year ended December 31, 2008. These reductions were partially offset by net proceeds received from our registered direct offering, completed in February 2008, of approximately \$49.1 million.

The \$49.7 million of cash used in operations for the year ended December 31, 2008 represents a \$9.0 million increase from the \$40.7 million of cash used in operations during 2007. This increase was primarily due to cash used in reducing in our accounts payable and accrued liabilities during the year ended December 31, 2008, as compared to an increase in accounts payable and liabilities during the year ended December 31, 2007. This fluctuation in the accounts payable and accrued liabilities balances is mostly due to timing of payments and progress of our clinical development program, as we completed enrollment in our clinical trials during 2008. Also contributing to the increase in cash used in operations during 2008 was a reduction in interest earned on our investments, primarily from lower average yields, and additional interest expense incurred on our increased debt obligations.

During the year ended December 31, 2008, our net current and long-term debt balances decreased \$5.2 million as compared to December 31, 2007. This decrease was due to \$5.6 million of principal payments during 2008, partially offset by the amortization of warrant costs issued in connection with the loan agreements and the accrual of the term loan final payment on our \$15.0 million credit facility. As of December 31, 2008, we had 7 equal monthly payments remaining on our \$7.0 million credit facility. Under our \$15.0 million credit facility we had 24 equal monthly payments remaining as well as the term loan final payment.

As of December 31, 2008, our net property and equipment balance decreased by \$0.6 million to \$4.5 million, from \$5.1 million at December 31, 2007. This decrease was due to an impairment charge of \$2.4 million taken on our Omigard manufacturing equipment and depreciation of \$0.5 million on our assets during 2008, partially offset by \$1.7 million of capital equipment expenditures. The capital expenditures during 2008 were primarily for the potential commercial manufacturing of Omigard and Acetavance, as well as computer related expenditures our information technology infrastructure.

Sources of Liquidity

Since inception, our operations have been financed primarily through the issuance of equity securities, in both public and private offerings. From our inception through December 31, 2008, we have received net proceeds of approximately \$184.7 million from the sale of shares of our preferred and common stock. Additionally, in February 2009, we raised aggregate gross proceeds of approximately \$86.6 million through a private placement by issuing 12,039,794 shares of common stock and warrants to purchase up to 6,019,897 shares of common stock. Through December 31, 2008, the sale of shares of our preferred and common stock were as follows:

- from July 2004 to December 2008 (excluding our initial public offering and February 2008 registered direct offering), we issued and sold a total of 2,316,073 shares of common stock to our founders, employees, directors and consultants for aggregate net proceeds of \$0.8 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; and
- 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.

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 at the fixed rate of 11.47%. In November 2007, we amended the \$7.0 million loan and security agreement and entered into the Second Amendment to Loan and Security Agreement with the same parties and GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services, Inc.), to secure an additional \$15.0 million credit facility. In December 2007, we drew down \$15.0 million under the Second Amendment in two separate draws of \$5.0 million and \$10.0 million with fixed interest rates of 7.83% and 7.74%, respectively, net of a loan fee of less than \$0.1 million. In February 2007, we began making the first of 30 equal principal and interest payments on the \$7.0 million loan and in July 2008 we began making the first of 30 equal monthly principal and interest payments to fully amortize the balance on the \$15.0 million credit facility. As of December 31, 2008, we had no further credit available under these agreements. In connection with each credit facility, we issued warrants to the lenders to purchase shares of our stock. See Note 5 to the Notes to Financial Statements in Item 8 of this Annual Report on Form 10-K for further discussion.

Capital Resources

Our current cash and cash equivalent balances are currently our principal sources of liquidity. In February 2009, we raised additional aggregate gross funds of approximately \$86.6 million through the issuance of 12,039,794 shares of common stock and warrants to purchase up to 6,019,897 shares of common stock. We believe that with the proceeds of this recent financing together with our cash and cash equivalent balance at December 31, 2008, we will satisfy our requirements for projected working capital, capital expenditures and debt servicing, at a minimum, through the next eighteen months. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available financial resources faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to the rate of progress and costs of our efforts to prepare for the submission of an NDA for Acetavance and any other product candidates that we may license or acquire, and the potential that we may need to conduct additional clinical trials and other studies to support applications for regulatory approval. Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources generated from the proceeds of offerings of our equity securities and our existing borrowings under our amended loan and security agreement. In addition, we may finance future cash needs through the sale of additional equity securities, strategic collaboration agreements and debt financing. However, we have drawn down all available amounts under our existing amended loan and security agreement, and we may not be successful in obtaining strategic collaboration agreements or in receiving milestone or royalty payments under those strategic collaboration agreements. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted.

We cannot be sure that our existing cash and investment resources will be adequate, that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. As a result of the recent volatility in the capital markets, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may adversely affect our ability to obtain

additional financing on terms acceptable to us, or at all. If these market conditions continue, they may limit our ability to timely replace maturing liabilities and to access the capital markets to meet liquidity needs. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our development programs, relinquish some or even all rights to product candidates at an earlier stage of development 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. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring additional debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

We have invested a substantial portion of our available cash in money market funds placed with reputable financial institutions for which credit loss is not anticipated. The capital markets have recently been highly volatile and there has been a lack of liquidity for certain financial instruments, especially those with exposure to mortgage-backed securities and auction rate securities. This lack of liquidity has made it difficult for the fair value of these types of instruments to be determined. As of December 31, 2008 our holdings consisted of money market funds invested solely in U.S. government agency securities and U.S. treasuries where an actively traded market is observed and through which values are determined. These funds do not hold auction rate securities. To date, we have not incurred any realized losses on our investment securities.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2008.

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, 2008 (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	\$15,503	\$ 8,507	\$6,996	\$—	\$—
Operating leases ⁽¹⁾	4,473	1,142	2,398	933	—
Process development and facility upgrades ⁽²⁾	1,382	1,382	—	—	—
License obligations ⁽³⁾	—	—	—	—	—
Total⁽⁴⁾	\$21,358	\$11,031	\$9,394	\$933	\$—

(1) The amounts presented represent commitments for minimum lease payments related to leases of office space and certain equipment under non-cancelable operating leases. The amounts have not been reduced by future commitments under sublease agreements.

(2) The amounts presented represent our commitments for the completion of pre-commercialization manufacturing development activities related to our development and supply agreement with Baxter and our long-term supply agreement with Solvay. Our five-year agreement with Baxter also requires that we purchase a minimum number units of Acetavance each year following regulatory approval of Acetavance, or pay Baxter an amount equal to the per-unit purchase price multiplied by the amount of the shortfall. Our seven-year agreement with Solvay requires that we purchase a majority of our aggregate annual requirements of Omiganan from Solvay. We have also agreed to pay development fees to Solvay upon the completion of specified manufacturing development activities and studies relating to Omiganan. However as the purchase commitments under these agreements are dependent upon the progress of our development program, the placement of purchase orders and/or the timing of the potential regulatory approval of our drug candidates, we are unable to estimate with certainty the future cost of the purchase obligations, if any, we will incur under these agreements. As a result of the discontinuation of our development program for Omigard, we are currently considering our options under our supply and license agreements with Solvay.

We would not be required to pay the development, license transfer or other fees called for under these agreements if we exercise our termination rights, and we believe that the expenses associated with the termination of these agreements would be minimal.

- (3) Under our license agreements, we may be required to make future payments of up to \$67.0 million, due upon the occurrence of certain milestones related to regulatory or commercial events. We may also be required to pay royalties on any net sales of the licensed products under those agreements. License payments may be increased based on the timing of various milestones and the extent to which the licensed technologies are pursued for other indications. These milestone payments and royalty payments under our license agreements are not included in the table above because at this time we cannot determine when, or if, the related milestones will be achieved or the events triggering the commencement of payment obligations will occur.
- (4) We also enter into agreements with third parties to manufacture our product candidates, conduct our clinical trials and perform data collection and analysis. Our payment obligations under these agreements depend upon the progress of our development programs. Therefore, we are unable at this time to estimate with certainty the future costs we will incur under these agreements. In addition, we enter into unconditional purchase obligations with various vendors and suppliers of goods and services in the normal course of operations through purchase orders or other documentation, or that are undocumented except for an invoice. Such unconditional purchase obligations are generally outstanding for periods less than a year and are settled by cash payments upon delivery of goods and services and are not reflected in this line item.

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

Cash and Cash Equivalents

Our cash and cash equivalents as of December 31, 2008 consisted of cash and money market funds invested solely in U.S. government agency securities and U.S. treasuries. The funds in which we invest have not incurred losses on their investments, nor have they imposed limits or restrictions on redemptions. Further, these funds have enrolled in the U.S. Treasury's Temporary Guarantee Program for Money Market Funds, protecting the principal value held in the funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. 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 investment securities available-for-sale that we may invest in could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment securities available-for-sale 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 10% change in interest rates.

Recently, there has been concern in the credit markets regarding the value of a variety of mortgage-backed and auction rate securities and the resultant effect on various securities markets. Our cash is invested 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. 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. Our money market accounts are invested solely in U.S. government agency securities and U.S. treasuries. 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.

In addition, continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to

increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

Debt

The loans under our amended loan and security agreement have fixed interest rates. Consequently, we do not have significant interest rate cash flow exposure on our debt. The aggregate principal balance of the loans, net of the loan discount, under the agreement at December 31, 2008 was \$13.8 million, and is collateralized by substantially all of our assets (excluding intellectual property). Under the terms of the agreement, we are precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and are subject to various non-financial covenants and prepayment penalties.

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Cadence Pharmaceuticals, Inc. (a development stage company) as of December 31, 2008 and 2007, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2008 and for the period from May 26, 2004 (Inception) through December 31, 2008. 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, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008 and for the period from May 26, 2004 (Inception) through December 31, 2008, 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, 2008, 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 12, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 12, 2009

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

BALANCE SHEETS

	December 31,	
	2008	2007
Assets		
Current assets:		
Cash and cash equivalents	\$ 47,627,246	\$ 55,392,921
Restricted cash	2,195,696	1,981,848
Prepaid expenses	144,118	751,046
Other current assets	75,556	208,275
Total current assets	50,042,616	58,334,090
Property and equipment, net	4,477,020	5,139,538
Restricted cash	537,586	885,434
Other assets	90,792	252,963
Total assets	\$ 55,148,014	\$ 64,612,025
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,877,854	\$ 1,974,991
Accrued liabilities	9,063,310	13,901,770
Current portion of long-term debt	7,694,173	5,617,928
Other current liabilities	22,048	—
Total current liabilities	21,657,385	21,494,689
Deferred rent	952,274	1,224,869
Long-term debt, less current portion and discount of \$377,396 and \$642,130, respectively	6,098,113	13,412,349
Other long-term liabilities	—	22,048
Total liabilities	28,707,772	36,153,955
Commitments and contingencies (Note 6)		
Stockholders' equity :		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2008 and 2007, respectively	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized, 38,363,985 shares and 29,112,755 shares issued and outstanding at December 31, 2008 and 2007, respectively	3,836	2,911
Additional paid-in capital	197,964,600	142,879,979
Accumulated other comprehensive income	—	4,524
Deficit accumulated during the development stage	(171,528,194)	(114,429,344)
Total stockholders' equity	26,440,242	28,458,070
Total liabilities and stockholders' equity	\$ 55,148,014	\$ 64,612,025

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF OPERATIONS

	Year Ended December 31,			Period from May 26, 2004 (Inception) through December 31, 2008
	2008	2007	2006	
Operating expenses:				
Research and development	\$ 40,018,204	\$ 41,781,357	\$ 47,826,761	\$ 137,635,905
Marketing	2,983,796	2,865,804	810,315	6,941,390
General and administrative	11,146,212	9,586,705	4,946,121	27,967,994
Other	2,384,251	—	—	2,384,251
Total operating expenses	<u>56,532,463</u>	<u>54,233,866</u>	<u>53,583,197</u>	<u>174,929,540</u>
Loss from operations	(56,532,463)	(54,233,866)	(53,583,197)	(174,929,540)
Other (expense) income:				
Interest income	1,530,172	3,404,447	1,944,908	7,144,692
Interest expense	(1,916,315)	(867,524)	(497,617)	(3,281,456)
Other expense	(180,244)	(16,611)	(37,035)	(461,890)
Total other (expense) income, net ..	<u>(566,387)</u>	<u>2,520,312</u>	<u>1,410,256</u>	<u>3,401,346</u>
Loss before income tax	<u>(57,098,850)</u>	<u>(51,713,554)</u>	<u>(52,172,941)</u>	<u>(171,528,194)</u>
Net loss	<u>\$(57,098,850)</u>	<u>\$(51,713,554)</u>	<u>\$(52,172,941)</u>	<u>\$(171,528,194)</u>
Basic and diluted net loss per share ⁽¹⁾	<u>\$ (1.55)</u>	<u>\$ (1.81)</u>	<u>\$ (10.07)</u>	
Shares used to compute basic and diluted net loss per share ⁽¹⁾	<u>36,823,660</u>	<u>28,572,833</u>	<u>5,181,920</u>	

⁽¹⁾ As a result of the issuance of 6,900,000 shares of common stock in the Company's initial public offering in the fourth quarter of 2006, the conversion of the Company's preferred stock into 19,907,605 shares of common stock upon completion of the Company's initial public offering, and the issuance of 9,240,307 shares of common stock pursuant to an effective shelf registration in the first quarter of 2008, there is a lack of comparability in the per share amounts between the 2008, 2007 and 2006 periods presented. Please see Note 2 of the Notes to Financial statements for further discussion.

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY—Continued

	Series A-1 to A-3 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount					
Issuance of warrants in November to purchase 50,331 shares of common stock at \$12.67 per share	—	—	—	—	473,876	—	—	473,876	
Cashless warrant exercise in March at \$15.04 per share	—	—	35,325	4	(4)	—	—	—	
Net repurchase of common stock from option repurchases under equity compensation plans	—	—	(15,290)	(2)	7,912	—	—	7,910	
Stock-based compensation	—	—	—	—	4,340,305	—	—	4,340,305	
Unrealized loss on investment securities	—	—	—	—	—	(59,509)	—	(59,509)	\$ (59,509)
Net Loss	—	—	—	—	—	—	(51,713,554)	(51,713,554)	(51,713,554)
Balance at December 31, 2007 ...	—	—	29,112,755	2,911	142,879,979	4,524	(114,429,344)	28,458,070	\$(51,773,063)
Registered direct offering of common stock, net of \$204,222 offering costs in February at \$5.34 per share	—	—	9,240,307	924	49,138,093	—	—	49,139,017	
Issuance of common stock from option exercises under equity compensation plans	—	—	10,923	1	8,929	—	—	8,930	
Stock-based compensation	—	—	—	—	5,937,599	—	—	5,937,599	
Unrealized loss on investment securities	—	—	—	—	—	(4,524)	—	(4,524)	\$ (4,524)
Net Loss	—	—	—	—	—	—	(57,098,850)	(57,098,850)	(57,098,850)
Balance at December 31, 2008 ...	—	\$—	38,363,985	\$3,836	\$197,964,600	\$ —	\$(171,528,194)	\$ 26,440,242	\$(57,103,374)

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF CASH FLOWS

	Year Ended December 31,			Period from May 26, 2004 (Inception) through December 31, 2008
	2008	2007	2006	
Operating activities				
Net loss	\$(57,098,850)	\$(51,713,554)	\$(52,172,941)	\$(171,528,194)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	529,646	515,763	221,681	1,312,355
Loss on disposal of assets	31,089	—	37,034	68,123
Impairment of long-lived assets	2,353,162	—	—	2,353,162
Impairment of available for sale securities	176,539	—	—	404,539
Stock-based compensation	5,937,599	4,340,305	2,134,958	12,413,673
Non-cash interest expense	31,108	8,622	7,535	47,266
Amortization of discount on note payable	264,734	106,190	84,128	455,051
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	689,647	(153,505)	(322,238)	(312,269)
Accounts payable	3,017,446	(98,735)	1,087,289	4,721,782
Accrued liabilities and other liabilities	(5,619,868)	6,320,244	7,210,292	8,340,887
Net cash used in operating activities	<u>(49,687,748)</u>	<u>(40,674,670)</u>	<u>(41,712,262)</u>	<u>(141,723,625)</u>
Investing activities				
Purchases of marketable securities	—	—	—	(7,450,000)
Maturities of marketable securities	—	—	7,000,000	7,000,000
Restricted cash	134,000	(1,286,152)	(1,581,130)	(2,733,282)
Purchases of property and equipment	(1,742,761)	(2,096,683)	(2,509,063)	(6,511,512)
Proceeds from the sale of property and equipment	195	—	—	195
Net cash (used in) provided by investing activities	<u>(1,608,566)</u>	<u>(3,382,835)</u>	<u>2,909,807</u>	<u>(9,694,599)</u>
Financing activities				
Proceeds from issuance of common stock	49,147,947	23,985	56,827,683	106,131,115
Disbursements from repurchase of common stock	—	(16,075)	—	(19,075)
Proceeds from sale of preferred stock, net	—	—	53,775,013	78,933,748
Borrowings under debt agreements	—	14,955,000	7,000,000	21,955,000
Principal payments under debt agreements	(5,617,308)	(2,338,010)	—	(7,955,318)
Net cash provided by financing activities	<u>43,530,639</u>	<u>12,624,900</u>	<u>117,602,696</u>	<u>199,045,470</u>
Net (decrease) increase in cash and cash equivalents	<u>(7,765,675)</u>	<u>(31,432,605)</u>	<u>78,800,241</u>	<u>47,627,246</u>
Cash and cash equivalents at beginning of period	55,392,921	86,825,526	8,025,285	—
Cash and cash equivalents at end of period	<u>\$ 47,627,246</u>	<u>\$ 55,392,921</u>	<u>\$ 86,825,526</u>	<u>\$ 47,627,246</u>
Supplemental disclosures				
Issuance of warrants in connection with loan and security agreement	\$ —	\$ 473,876	\$ 313,572	\$ 787,448
Assets acquired through lease concessions	\$ —	\$ —	\$ 1,190,530	\$ 1,190,530
Unrealized (loss) gain on investment securities	\$ (4,524)	\$ (59,509)	\$ 64,033	\$ —
Cash paid for interest and fees	\$ 1,483,420	\$ 693,288	\$ 339,002	\$ 2,515,710

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 its product portfolio; organizational activities, including recruiting personnel, establishing office facilities; and raising capital to fund these activities. To date, the Company has in-licensed rights to two late-stage product candidates, Acetavance™, an intravenous formulation of acetaminophen, and Omigard™, an omiganan pentahydrochloride 1% aqueous gel. We have completed the clinical trials for Acetavance that are required for submission of an application for regulatory approval. In March 2009, the Company announced that its Phase III clinical trial of Omigard did not meet its primary objective, and that it was discontinuing its development efforts for this product candidate because the results would not support a New Drug Application ("NDA") submission. At the same time, the Company announced that it would implement cost reduction measures and restructure its operations to make additional resources available for its Acetavance development program and other operating activities. The Company plans to submit an NDA, to the U.S. Food and Drug Administration ("FDA") for Acetavance in the second quarter of 2009. Since the Company has not begun principal operations of commercializing Acetavance, the Company is considered to be a development stage company as defined in Statement of Financial Accounting Standards ("SFAS") No. 7, *Accounting and Reporting by Development Stage Enterprises*.

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, available-for-sale securities, accounts payable and accrued liabilities. 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, accounts payable and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The fair value of available-for-sale securities is based upon market prices quoted on the last day of the fiscal period.

Effective January 1, 2008, the Company adopted the provisions of SFAS No. 157, *Fair Value Measurement*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements, but does not require any new fair value measurements. SFAS No. 157's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect

CADENCE PHARMACEUTICALS, INC.
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NOTES TO FINANCIAL STATEMENTS—Continued

readily obtainable data from independent sources, while unobservable inputs reflect market assumptions. SFAS No. 157 classifies these inputs into the following fair value hierarchy:

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

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

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

Currently, all of the Company's financial instruments are valued using level 1 inputs. The following table presents further detail of the financial instruments carried at fair value on the Company's balance sheet as of December 31, 2008:

<u>Description</u>	<u>Quoted market prices in active markets (Level 1)</u>	<u>Internal models with significant observable market parameters (Level 2)</u>	<u>Internal models with significant unobservable market parameters (Level 3)</u>	<u>Total carrying value in the balance sheet</u>
Cash and cash equivalents:				
Money market funds	\$47,331,056	\$—	\$—	\$47,331,056
Other assets:				
Available-for-sale equity securities	45,461	—	—	45,461
Total assets at fair value	<u>\$47,376,517</u>	<u>\$—</u>	<u>\$—</u>	<u>\$47,376,517</u>

Cash Equivalents

The Company considers all highly liquid investments purchased with original 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, 2008 and 2007, the Company's cash equivalents were \$47,331,056 and \$54,301,722, respectively.

Marketable Securities

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

In accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, the Company has classified its investment holdings as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies. During the year ended December 31, 2008, the Company recorded an impairment charge to reduce the value of its sole available-for-sale security by \$176,539 as its market value was significantly below its carrying value. See Note 3 for further discussion.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

Concentration of Credit Risk

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

Segment Information

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

Property and Equipment

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

For the years ended December 31, 2008, 2007 and 2006, the Company recorded depreciation expense of \$529,646, \$515,763 and \$221,681, respectively. Since May 26, 2004 (inception) through December 31, 2008, the Company has incurred \$1,312,355 of depreciation expense.

Impairment of Long-Lived Assets

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal 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.

The Company recorded an impairment charge of \$2,353,162 for the year ended December 31, 2008 related to its Omigard manufacturing assets due to the discontinuation of its Omigard development program. The impairment charge is included in Other Operating Expenses. No similar impairments were recorded for the years ended December 31, 2007 or 2006. See Note 12 for further discussion.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

Research and Development

The Company accounts for research and development costs in accordance with SFAS No. 2, *Accounting for Research and Development Costs*. SFAS No. 2 specifies that research and development costs should be charged to expense until technological feasibility has been established for the product. Once technological feasibility is established, all product costs should be capitalized until the product is available for general release to customers. The Company has determined that technological feasibility for its product candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale. 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. Through December 31, 2008, the Company's historical research and development expenses relate predominantly to the in-licensing of Acetavance and Omigard, the related clinical trials for these product candidates and the preparation for their potential commercialization, including regulatory and manufacturing activities.

Income Taxes

Income taxes are accounted for under the asset and liability 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.

On July 13, 2006, the Financial Accounting Standards Board ("FASB") issued Financial Interpretation ("FIN") No. 48, *Accounting for Uncertainty in Income Taxes – An Interpretation of FASB Statement No. 109*. FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*, and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN No. 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN No. 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN No. 48 is effective for fiscal years beginning after December 15, 2006. See Note 9 for further discussion.

Stock-Based Compensation

The Company has stock-based compensation plans, which are described in Note 8. The Company accounts for awards issued from these plans under the provisions of SFAS No. 123(R), *Share-Based Payment*, adopted on January 1, 2006. SFAS No. 123(R) requires companies to estimate the fair value of stock-based payment award on the date of grant using an option pricing model. The Company currently uses the Black-Scholes option pricing model to estimate the fair value of its stock-based awards. This option pricing model involves a number of

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NOTES TO FINANCIAL STATEMENTS—Continued

estimates, including the expected lives of stock options, the Company's anticipated stock volatility and interest rates. Stock-based compensation expense recognized during the period is based on the value of the portion of awards that is ultimately expected to vest and thus the gross expense is reduced for estimated forfeitures.

Compensation expense for all stock-based payment awards was recognized using the straight-line method. The following table summarizes the average estimates the Company used in the Black-Scholes option pricing model for the years ended December 31, 2008, 2007 and 2006, to determine the fair value of stock options granted during each period:

	Year Ended December 31,		
	2008	2007	2006
Risk free interest rates	2.9%	4.6%	5.0%
Expected life in years	6.0 years	6.0 years	6.1 years
Expected dividend yield	0.0%	0.0%	0.0%
Expected volatility	70.0%	66.2%	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 Securities and Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 107 and No. 110, 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 also reflects the application of SAB No. 107, incorporating the historical volatility of comparable companies whose share prices are publicly available. 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, 2008, 2007 and 2006 at \$4.13, \$9.53 and \$5.98, respectively.

On June 14, 2006, the Company commenced the initial public offering process, and based on the preliminary valuation information presented by the underwriters for its initial public offering, the Company reassessed the value of the common stock used to grant equity awards back to June 30, 2005. The reassessment of fair value was completed by management, all of whom are related parties and without the use of an unrelated valuation specialist, who concluded that the stock options granted to employees and directors in May and June of 2006 were at prices that were below the reassessed values. In the reassessment process, the Company's management concluded that the original valuations did not give enough consideration to the impact of an initial public offering on the value of the common stock. Accordingly, for the 1,124,057 options granted at \$1.36 per share in May 2006, and for the 259,500 options granted in June 2006 at \$3.20 per share, the reassessed fair values were determined to be \$6.60 per share and \$7.70 per share, respectively. The reassessed values were determined by using the low end of the estimated offering range of \$11.00 per share (as set forth on the red-herring prospectus), less a marketability discount of 40% and 30%, respectively, which reflects the estimated risk of not completing the initial public offering. The reassessed fair values may not be reflective of fair market value that would result from the application of other valuation methods, including accepted valuation methods for tax purposes.

Stock-based compensation expense recognized under SFAS No. 123(R) for the years ended December 31, 2008, 2007 and 2006 was \$5,937,599, \$4,340,305 and \$2,134,958, respectively. Since May 26, 2004 (inception),

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NOTES TO FINANCIAL STATEMENTS—Continued

the Company has incurred \$12,413,673 of stock-based compensation expense. The table below summarizes the stock-based compensation expense included in the Company's statements of operations for the periods presented:

	Year Ended December 31,			Period from May 26, 2004 (Inception) through December 31, 2008
	2008	2007	2006	
Research and development	\$1,966,977	\$1,243,173	\$ 561,257	\$ 3,771,407
Marketing	61,119	32,808	1,171	95,098
General and administrative	3,909,503	3,064,324	1,572,530	8,547,168
Stock-based compensation expense included in operating expenses	5,937,599	4,340,305	2,134,958	12,413,673
Total stock-based compensation expense included in loss from operations	<u>\$5,937,599</u>	<u>\$4,340,305</u>	<u>\$2,134,958</u>	<u>\$12,413,673</u>

As of December 31, 2008, the total future compensation expense related to unvested stock options, net of estimated forfeitures, is expected to be approximately \$11,027,984. This expense is expected to be recognized over a weighted-average period of approximately 28 months. The total fair value of shares vested during 2008, 2007 and 2006 was \$6,339,912, \$4,602,921 and \$273,050, respectively.

Comprehensive Income (Loss)

The Company has applied SFAS No. 130, *Reporting Comprehensive Income*, which requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments and unrealized gains and losses on investments, are reported, net of their related tax effect, 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, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The actual net loss per share amounts for the years ended December 31, 2008, 2007 and 2006 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) 9,240,307 common shares pursuant to an effective shelf registration in the first quarter of 2008; (ii) 6,900,000 common shares issued by the Company in the fourth quarter of 2006, and (iii) the conversion of the Company's preferred stock into 19,907,605 common shares upon completion of the Company's initial public offering. 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 years ended December 31, 2008, 2007 and 2006.

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NOTES TO FINANCIAL STATEMENTS—Continued

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

	Year Ended December 31,		
	2008	2007	2006
Shares for basic and dilutive net loss per share:			
Weighted average common shares outstanding	37,094,918	29,107,093	5,958,035
Weighted average unvested common shares subject to repurchase	(271,258)	(534,210)	(776,115)
Denominator for basic and diluted earnings per share	36,823,660	28,572,883	5,181,920

At December 31, 2008, 2007 and 2006, options and other exercisable convertible securities totaling 3,851,451, 2,900,634 and 2,459,352 shares, respectively, were excluded from the calculation as their effect would have been antidilutive.

In February 2009, the Company issued 12,039,794 shares pursuant to a private placement. The effect of this transaction is not reflected in the loss per share calculation for the periods presented. See Note 12 for further discussion.

Recent Accounting Pronouncements

In April 2008, the FASB issued Financial Staff Position (“FSP”) No. FAS 142-3, *Determination of the Useful Life of Intangible Assets*. FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. The intent of FSP FAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141(R), *Business Combinations*, and other applicable accounting literature. FSP FAS 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company is currently reviewing the effects of FSP FAS 142-3 and does not anticipate that the adoption will have a material impact on its financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities—an amendment of FASB Statement No. 133*. SFAS No. 161 amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and intends to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity’s financial position, financial performance and cash flows. SFAS No. 161 also requires disclosure about an entity’s strategy and objectives for using derivatives, the fair values of derivative instruments and their related gains and losses. SFAS No. 161 is effective for reporting periods beginning after November 15, 2008, with early adoption encouraged. The Company is currently does not expect SFAS No. 161 to have a material impact on its financial statements.

3. Available-for-Sale Securities

As partial consideration the Company received from its acquisition of the development and commercialization rights to the Migenix, Inc. (“Migenix”) omiganan pentahydrochloride product candidate in July 2004, the Company acquired 617,284 shares of Migenix common stock (see Note 7 for further discussion of the acquisition of these shares). The Company accounts for these shares as available-for-sale securities and they are included as other non-current assets in the balance sheet. At the time of acquisition, the shares were recorded

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NOTES TO FINANCIAL STATEMENTS—Continued

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 determining if and when decreases in market value of the Company's equity positions below their cost are other-than-temporary, the Company examines historical trends in stock prices and the financial condition of the issuers. If the Company determines that a decline in value is other-than-temporary, the Company recognizes an impairment loss in the current period operating results to the extent of the decline. At December 31, 2008, the market value of the Company's equity position in Migenix was significantly below the Company's adjusted cost basis. The Company recorded an impairment charge to reduce the Company's cost basis to the fair value of the shares held as of December 31, 2008. The \$176,539 charge is included in Other expense on the Company's statement of operations for the year ended December 31, 2008. No similar impairment charges were recorded for the years ended December 31, 2007 and 2006, respectively.

The cost, gross unrealized holding gains, gross unrealized holding losses and fair value of the Company's available-for-sale security at December 31, 2008 and 2007 consisted of the following:

	<u>Adjusted Cost Basis</u>	<u>Gross Unrealized Holding Gains</u>	<u>Gross Unrealized Holding Losses</u>	<u>Fair Value</u>
At December 31, 2008				
Available-for-sale:				
Equity securities	\$ 45,461	\$ —	\$—	\$ 45,461
At December 31, 2007				
Available-for-sale:				
Equity securities	\$222,000	\$4,524	\$—	\$226,524

4. Selected Financial Statement Data

	<u>As of December 31,</u>	
	<u>2008</u>	<u>2007</u>
Property and equipment:		
Leasehold improvements	\$ 1,592,404	\$ 1,580,336
Computer equipment and software	607,319	544,273
Furniture and fixtures	427,811	421,178
Manufacturing equipment	—	123,303
Construction-in-process	3,008,972	3,213,617
	<u>5,636,506</u>	<u>5,882,707</u>
Less accumulated depreciation	(1,159,486)	(743,169)
Total	<u>\$ 4,477,020</u>	<u>\$ 5,139,538</u>
Accrued liabilities:		
Accrued patient costs	\$ 2,388,930	\$ 4,284,550
Accrued clinical research costs	623,444	2,893,214
Accrued manufacturing costs and equipment purchases	2,124,053	4,323,539
Accrued personnel costs	2,053,087	1,127,582
Other accrued liabilities	1,873,796	1,272,885
Total	<u>\$ 9,063,310</u>	<u>\$13,901,770</u>

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NOTES TO FINANCIAL STATEMENTS—Continued

5. 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 November 2007, the Company amended the Agreement and entered into the Second Amendment to Loan and Security Agreement (the “Second Amendment”) with the same parties and GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.), to secure an additional \$15,000,000 credit facility. In December 2007, the Company drew down \$15,000,000 under the Second Amendment in two separate draws of \$5,000,000 and \$10,000,000 with fixed interest rates of 7.83% and 7.74%, respectively, net of a \$45,000 loan fee (the “loan fee”). In addition to the principal and interest, the Company is required to pay \$375,000 at the termination of Second Amendment (the “term loan final payment”). The loan fee and the warrants issued in connection with the loan (as described below), have been recognized as a discount on the loan issuance which, together with the fixed interest rates, will be amortized to interest expense throughout the life of the loan using an effective interest rate of 9.56%. The term loan final payment is being accrued through interest expense over the life of the loan. All interest payable under the Second Amendment and the full amount of the term loan final payment must be paid upon any prepayment of the loan.

The loans are collateralized by substantially all the assets of the Company (excluding intellectual property). Under the terms of the Agreement, the Company may be precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and is subject to certain non-financial covenants and prepayment penalties. Upon the occurrence of an event of default, including a Material Adverse Change (as defined in the Agreement), the lenders may declare all outstanding amounts due and payable under the Agreement.

In August 2006, the Company began making the first of six monthly interest-only payments on the \$7,000,000 balance of the Agreement and in February 2007, began making the first of 30 equal monthly principal and interest payments. In January 2008, the Company began making the first of six monthly interest-only payments on the \$15,000,000 balance of the Second Amendment and in July 2008, began making the first of 30 equal monthly principal and interest payments. As of December 31, 2008 and 2007, the aggregate principal balance of the loans, net of the loan discount, included on the Company’s balance sheets was \$13,792,286 and \$19,030,277, respectively.

Warrants

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

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NOTES TO FINANCIAL STATEMENTS—Continued

In connection with the Second Amendment to the Agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc., the Company issued six fully exercisable warrants to the lenders to purchase an aggregate of 50,331 shares of the Company's common stock at an exercise price of \$12.67 per share, expiring November 30, 2014. The Company determined the fair value of these warrants to be \$473,876, using the Black-Scholes valuation model. The value of the warrants was recorded as a discount to the note payable, and will be amortized to interest expense over the expected term of the loan agreement. The warrants were valued using the following assumptions: risk-free interest rate of 3.64%; dividend yield of 0.0%; expected volatility of 70.0%; and a contractual term of seven years. As of December 31, 2008, all warrants related to the Second Amendment were outstanding.

6. Commitments and Contingencies

Leases

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

The Company also leases certain office equipment under operating leases with terms that range from one to four years and expire in 2012. As of December 31, 2008, the total future minimum payments under operating leases, including rent and office equipment, were as follows:

2009	\$1,142,044
2010	1,178,787
2011	1,218,953
2012	933,552
2013	—
Thereafter	—
	<u>\$4,473,336</u>

Future minimum lease payments have not been reduced by future minimum sublease rentals of \$163,054. Rent expense, net of sublease rent income, for the years ended December 31, 2008, 2007 and 2006 was \$568,134, \$576,124 and \$772,646, respectively. Since May 26, 2004 (inception) through December 31, 2008, the Company has incurred net rent expense of \$2,121,240.

Supply Agreements

Baxter Healthcare Corporation

In July 2007, the Company entered into a development and supply agreement (the "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 Acetavance.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

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

The Agreement also requires the Company to fund specified improvements at Baxter's manufacturing facility and purchase certain equipment for use by Baxter in manufacturing Acetavance. As of December 31, 2008, the Company has reimbursed Baxter for a portion of the facility improvements and has expensed the costs as they have been incurred. The equipment purchased for the manufacturing of Acetavance to which the Company retains title is being capitalized as it has alternative future uses and will be amortized over the life of the equipment. At the time of termination, the Agreement requires the Company to reimburse Baxter for all reasonable costs for the de-installation of the Company's equipment and the restoration of Baxter's manufacturing facility to its pre-installation condition. The Company is not able to reasonably estimate the cost and the timing of these expenses at this time and therefore cannot reasonably estimate the fair value of the retirement obligation.

In anticipation of the execution of the Agreement, the Company entered into an irrevocable standby letter of credit in favor of Baxter in January 2007. The letter of credit was for an initial amount of \$3,268,000 and was based on anticipated costs to be incurred by Baxter for the improvements at Baxter's manufacturing facility and the purchase of equipment to be used by Baxter in the manufacturing of the finished drug product. Under the terms of the Agreement, the amount of the letter of credit may be reduced on a quarterly basis following the execution of the Agreement for the costs the Company has reimbursed Baxter to fund the specified facility improvements or equipment purchases. As of December 31, 2008, at the request of the Company and based upon the costs reimbursed to Baxter by the Company, the letter of credit had been reduced by \$1,768,000 to \$1,500,000. The letter of credit in favor of Baxter is collateralized by a certificate of deposit which may be drawn down in part or in whole by Baxter in the event the Company fails to perform its obligations to fund the specified facility improvements or equipment purchases. As of December 31, 2008, the certificate of deposit had been reduced to \$1,500,000 in accordance with the reduction in the letter of credit.

Solvay SA

On December 1, 2008, the Company entered into a long-term supply agreement (the "Supply Agreement") with Solvay SA ("Solvay") for a bulk peptide product that contains omiganan pentahydrochloride ("Omiganan"), the active ingredient in the Company's former Omigard product candidate. As a result of the discontinuation of its development program for Omigard, the Company is currently considering its options under the supply agreement with Solvay. The purchase commitments under the supply agreement are dependant upon the progress of the Omigard development program, and the Company would not be required to pay the development or other fees called for under this agreement if it exercises its termination rights. The Company believes that the expenses associated with such termination would be minimal, and that termination of the agreement would not have a material impact on its financial statements.

Pursuant to the terms of the Supply Agreement, the Company has agreed that Solvay will serve as the Company's primary supplier for Omiganan and is obligated to purchase a majority of its aggregate annual

CADENCE PHARMACEUTICALS, INC.
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NOTES TO FINANCIAL STATEMENTS—Continued

requirements of Omiganan from Solvay. Pricing of Omiganan will be based upon the quantity of Omiganan purchased by the Company for the applicable year. The Company has also agreed to pay development fees to Solvay upon the completion of specified manufacturing development activities and studies relating to Omiganan, a portion of which has already been incurred as of December 31, 2008. These development fees will be expensed as incurred.

The Supply Agreement has an initial term that terminates upon the seven-year anniversary of the date that the Company notifies Solvay that the Phase III clinical trial of Omigard has met its primary endpoint and the Company intends to file an NDA with the FDA. The Supply Agreement will automatically renew for successive one-year periods thereafter, unless either party provides at least three-years' prior written notice of termination to the other party. In addition, the Supply Agreement may be terminated: (i) by either party after written notice in the event of a material uncured breach of the Supply Agreement by the other party, (ii) by either party after written notice if the other party ceases to do business, is dissolved or wound up, or makes any assignment of substantially all of its assets for the benefit of creditors, (iii) by the Company after written notice in the event that a third party asserts that the activities carried out under the Supply Agreement infringe its intellectual property rights, (iv) by the Company after written notice effective upon the termination of its license agreement with Migenix, Inc. pertaining to Omigard, or (v) by Solvay in the event that the Company does not provide the contemplated notification to Solvay regarding the clinical trial results and NDA filing as scheduled.

In connection with the Supply Agreement, the Company also entered into a License Agreement (the "License Agreement") with Solvay, pursuant to which Solvay has agreed to grant the Company the right to grant a sublicense under Solvay's relevant patent rights and know-how to a secondary source for the supply of Omiganan to the Company. Pursuant to the terms of the License Agreement, upon the date on which the Company notifies Solvay that the Phase III clinical trial has met its primary endpoint and the Company intends to file an NDA for this product candidate, Solvay agrees to grant the Company the non-exclusive and non-transferable right to grant to a secondary source of supply a sole worldwide and non-transferable sublicense under specified Solvay patents, know-how and improvements for the purpose of manufacturing, producing, supplying and performing development activities related to Omiganan or a drug product containing, or made using, Omiganan. Under the License Agreement, Solvay will receive (i) a one-time license fee and a one-time know-how transfer fee, each payable following the date on which the licenses are granted to the Company, and (ii) royalties, payable on a yearly basis, on Omiganan purchased from the secondary source by the Company. The royalties are subject to reduction in the event that any quantity of Omiganan purchased from the secondary source could not have been purchased from Solvay without exceeding Solvay's production capacity for the year. The Company will also pay to Solvay a per-diem fee and will bear reasonable travel expenses related to any specialist providing technical assistance services under the License Agreement.

The License Agreement has an initial term that terminates upon the later of (A) the twelve-year anniversary of the achievement of specified milestones or (B) the date of expiration of specified patent claims related to Omiganan that would be infringed by the manufacture and supply of Omiganan made by the secondary source. The License Agreement may also be terminated: (i) by either party after written notice in the event of a material uncured breach of the License Agreement by the other party, (ii) by either party after written notice if the other party ceases to do business, is dissolved or wound up, or makes any assignment of substantially all of its assets for the benefit of creditors, subject to limited exceptions, (iii) by either party in the event the Supply Agreement is terminated under specified circumstances, (iv) by Solvay after written notice in the event any of the Company, the secondary source, or entities or persons which control or are controlled by the secondary source disputes the validity of the Solvay know-how and patents, or any improvement of Solvay, and such dispute remains uncured, or, (v) by the Company after written notice at any time and for any reason.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

7. License Agreements and Acquired Development and Commercialization Rights

In July 2004, the Company in-licensed from Migenix the technology and the exclusive development and commercialization rights to its omiganan pentahydrochloride product candidate for the prevention and treatment of device-related, wound-related and burn-related infections in North America and Europe. At the time the agreement was executed, the Company paid a \$2,000,000 up-front fee, of which \$1,550,000 was allocated to the value of the acquired technology and \$450,000 was recorded as other long-term assets in the accompanying balance sheet for the 617,284 shares of Migenix common stock acquired in the transaction. The Company may also be required to make future milestone payments totaling up to \$27,000,000 upon the achievement of various milestones related to regulatory or commercial events. In addition, the Company is obligated to pay a royalty on future net sales (as defined in the Migenix collaboration and license agreement) of the licensed products and has the right to grant sublicenses to affiliates. All payments related to the Migenix agreement (other than for the acquisition of common stock) have been recognized as research and development expense. As a result of the discontinuation of its development program for Omigard, the Company is currently evaluating its options under its license agreement with Migenix and does not anticipate the decision will have a material impact on its financial statements.

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

8. Stockholders' Equity

Stock Split

In October 2006, the Company's board of directors and stockholders approved a one-for-four reverse stock split of the Company's outstanding common stock. These financial statements and accompanying notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

Initial Public Offering

In the fourth quarter of 2006, the Company completed an initial public offering whereby the Company sold 6,900,000 shares of common stock at \$9.00 per share and received net proceeds of \$55,895,148 (after underwriting discounts and offering costs). In connection with the Company's initial public offering, the 79,630,455 outstanding shares of convertible preferred stock converted into 19,907,605 shares of common stock.

Concurrent with the closing of the Company's initial public offering, the Company filed its amended and restated certificate of incorporation, which authorized total capital stock of 110,000,000 shares, \$0.0001 par value, of which 100,000,000 shares were designated Common Stock and 10,000,000 shares were designated Preferred Stock. The holders of Common Stock are entitled to one vote for each share of Common Stock for all matters submitted to a vote of the Company's stockholders. Although no shares of Preferred Stock are currently issued, if such shares were issued, the designation, powers, preferences, and rights of any such series would be determined by the Company's board of directors at the time of issuance.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

Shelf Registration

On November 30, 2007, the Company filed a shelf registration statement that was declared effective by the SEC on December 11, 2007. This shelf registration statement allows the Company to sell shares of its common stock from time to time in one or more offerings, with an aggregate offering price of up to \$100,000,000. In February 2008, the Company issued 9,240,307 shares of its common stock at a purchase price of \$5.34 per share pursuant to the shelf registration. The registered direct offering raised proceeds, net of offering costs, of \$49,139,017. The purchasers in the offering were comprised of new investors and existing stockholders, including executive officers and directors of the Company.

Stock Options

In 2006, the Company adopted the 2006 Equity Incentive Award Plan (the “2006 Plan”) in connection with the Company’s initial public offering which became effective on October 24, 2006. Upon adoption of the 2006 Plan, the Company restricted future grants from its 2004 Equity Incentive Award Plan (the “2004 Plan”). The 2006 Plan initially reserved 2,100,000 shares of common stock for future issuance and allowed for the initial 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, 2008, options to purchase 73,054 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. An aggregate of 20,000,000 shares of common stock may be issued over the 10-year term of the 2006 Plan. At January 1, 2008, the amount of shares authorized for future issuance under the 2006 Plan was increased by 1,018,939 shares under this provision, as approved by the board of directors.

The following table presents shares authorized, available for future grant and outstanding under each of the Company’s plans at December 31, 2008:

	<u>Authorized</u>	<u>Available</u>	<u>Outstanding</u>
2004 Equity Incentive Plan	2,711,174	—	1,583,180
2006 Equity Incentive Plan	3,282,765	1,236,515	2,046,250
	<u>5,993,939</u>	<u>1,236,515</u>	<u>3,629,430</u>

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

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NOTES TO FINANCIAL STATEMENTS—Continued

The following table summarizes the Company's stock option activity as of December 31, 2008, 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	2,466,825	\$ 6.51		
Granted	1,302,325	\$ 6.43		
Exercised	(10,923)	\$ 0.82		
Cancelled	<u>(128,797)</u>	<u>\$11.35</u>		
Options outstanding at end of period	<u>3,629,430</u>	<u>\$ 6.33</u>	<u>8.23</u>	<u>\$9,696,578</u>
Options exercisable at end of period	<u>1,970,929</u>	<u>\$ 4.48</u>	<u>7.57</u>	<u>\$8,203,275</u>

The aggregate intrinsic value of options exercised during 2008, 2007 and 2006 was \$71,556, \$332,642 and \$3,295,433, respectively. As of December 31, 2008, 171,690 shares acquired through the early exercise of options were subject to repurchase by the Company until they vest in accordance with the vesting schedule applicable to the underlying option.

9. 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, 2008 and 2007, and has recognized no interest and/or penalties in the Company's statement of operations for the years ended December 31, 2008, 2007 and 2006, respectively.

The Company adopted the provisions of FIN No. 48 on January 1, 2007. On the date of adoption of FIN No. 48, 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 included in the Company's balance sheet at December 31, 2008 and 2007, respectively.

The Company has not completed a 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 \$53,762,000 and research and development credits of approximately \$3,910,000 generated through 2008 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 under FIN No. 48. 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.

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NOTES TO FINANCIAL STATEMENTS—Continued

Significant components of the Company's deferred tax assets for federal and state income taxes at December 31, 2008 and 2007 are shown below. A valuation allowance has been established as realization of such deferred tax assets has not met the more likely than not threshold requirement under SFAS No. 109.

	December 31,	
	2008	2007
Deferred tax assets:		
Net operating loss carryforwards	\$ —	\$ —
Tax credit carryforwards	—	—
Capitalized research and development	8,726,000	9,514,000
Other, net	4,559,000	2,765,000
	13,285,000	12,279,000
Valuation allowance for deferred tax assets	(13,285,000)	(12,279,000)
Net deferred taxes	\$ —	\$ —

At December 31, 2008, the Company had federal and state net operating loss carryforwards of approximately \$131,944,000 and \$131,946,000, respectively, and federal and state research and development tax credit carryforwards of approximately \$3,065,000 and \$1,299,000, respectively. The net operating loss carryforwards will begin to expire in 2024 for federal purposes and 2014 for state purposes unless previously utilized, and the federal tax credit carryforwards will begin to expire in 2024 unless previously utilized. The state research tax credits carryforward indefinitely.

10. Employee Benefit Plan

The Company has a qualified retirement plan under the provisions of Section 401(k) of the Internal Revenue Code covering substantially all employees. Employees may contribute up to 100% of their annual compensation up to the maximum annual amount prescribed by the IRS. The Company may elect to make a discretionary contribution or match a discretionary percentage of employee contributions. During 2008, 2007 and 2006, the Company elected not to make any contributions to the plan.

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NOTES TO FINANCIAL STATEMENTS—Continued

11. 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, 2008 and 2007 are as follows:

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

	Fiscal Year 2007 Quarters				Total
	1st	2nd	3rd	4th	
Total operating expenses	\$10,371,579	\$ 15,657,285	\$ 13,602,799	\$ 14,602,203	\$ 54,233,866
Net loss	\$ (9,559,698)	\$(14,934,589)	\$(12,986,435)	\$(14,232,832)	\$(51,713,554)
Basic and diluted net loss per share ⁽¹⁾⁽²⁾	\$ (0.34)	\$ (0.52)	\$ (0.45)	\$ (0.50)	\$ (1.81)

- (1) Loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly net loss per share may not necessarily equal the total for the year.
- (2) In the first quarter of 2008, the Company issued 9,240,307 shares of its common stock at a purchase price of \$5.34 per share pursuant to the shelf registration. As a result, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented.
- (3) The Company recorded an impairment charge of \$2,353,162 for the fourth quarter of 2008 related to its Omigard manufacturing assets.

12. Subsequent Events

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 has a five-year term and is exercisable in cash or by net exercise for one share of common stock at a price of \$7.84.

The private placement raised gross proceeds of \$86,596,218. The purchasers in the offering were comprised of new investors and existing stockholders of the Company, including six funds affiliated with three directors of the Company. The securities sold in the private placement have not been registered under the Securities Act of 1933, as amended, or any state securities laws, and were sold pursuant to Regulation D of the Securities Act. These securities may not be offered or sold in the United States absent registration or pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws, and we have agreed to file a registration statement no later than March 20, 2009 covering the resale of the shares of common stock acquired by the investors and shares of common stock issuable upon exercise of the warrants acquired by the investors. The Company may be liable for liquidated damages to the investors if the registration statement is not declared effective by May 19, 2009 (if it does not become subject to review by the SEC), or by June 18, 2009 (if it becomes subject to review by the SEC). The amount of liquidated damages is one percent per month, subject to an aggregate cap of eight percent per calendar year, of the aggregate purchase price of the common shares then held by the investor that are registrable securities.

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(a development stage company)

NOTES TO FINANCIAL STATEMENTS—Continued

On March 12, 2009, the Company announced its decision to discontinue the development of its Omigard product candidate. Although the Company is continuing to evaluate its options under its license agreement with Migenix and Solvay covering Omigard, in connection with the discontinuation of the development of Omigard, the Company committed to a corporate restructuring in order to reduce costs. The restructuring, which may include a work force reduction, resulted in impairment charges in the fourth quarter of 2008 of \$2,353,162 on the Company's Omigard manufacturing equipment.

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, 2008 that has materially effected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

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

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

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

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

As of December 31, 2008, 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, 2008 and is included below.

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

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

We have audited Cadence Pharmaceuticals, Inc.'s (a development stage company) internal control over financial reporting as of December 31, 2008, 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, 2008, 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, 2008 and 2007, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2008 and for the period from May 26, 2004 (Inception) through December 31, 2008, of Cadence Pharmaceuticals, Inc. and our report dated March 12, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 12, 2009

Item 9B. Other Information

Not applicable.

PART III

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

Information required by this item will be included under the captions *Election of Directors, Corporate Governance and Other Matters, Executive Compensation and Other Information, and Section 16(a) Beneficial Ownership Reporting Compliance* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2008 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, 2008 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, 2008 pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference. The information required this item regarding our equity compensation plan is included in Item 5 of this Annual Report on Form 10-K.

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

Information required by this item will be included under the captions *Certain Relationships and Related Transactions* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2008 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, 2008 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 62 through 85, as follows:

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	62
Balance Sheets at December 31, 2008 and 2007	63
Statements of Operation for the years ended December 31, 2008, 2007 and 2006, and for the period from May 26, 2004 (inception) through December 31, 2008	64
Statements of Stockholders' Equity for the years ended December 31, 2008, 2007, 2006 and 2005, and for the period from May 26, 2004 (inception) through December 31, 2004	65
Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006, and for the period from May 26, 2004 (inception) through December 31, 2008	67
Notes to Financial Statements	68

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

(3) Exhibits.

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

Exhibit Number	Description of Exhibit
4.8	Form of Warrant to Purchase Stock issued to GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.), on November 30, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.9	Form of Warrant to Purchase Stock issued on February 18, 2009, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 20, 2009
10.1 [#]	Form of Director and Executive Officer Indemnification Agreement, incorporated herein by reference to the corresponding exhibit to Amendment No. 1 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on August 30, 2006
10.3 [#]	2004 Equity Incentive Award Plan and forms of option agreements thereunder, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-8 (File No. 333-138226) as filed with the SEC on October 26, 2006
10.5 [#]	2006 Equity Incentive Award Plan and forms of option and restricted stock agreements thereunder, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-8 (File No. 333-138226) as filed with the SEC on October 26, 2006
10.6	Form of Amended and Restated Restricted Common Stock Purchase Agreement, incorporated herein by reference to the corresponding exhibit to Amendment No. 1 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on August 30, 2006
10.9	Lease dated May 12, 2006 by and between the Registrant and Prentiss/Collins Del Mar Heights LLC, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006
10.10 [†]	Collaboration and License Agreement dated July 30, 2004 by and between the Registrant and Migenix Inc. (formerly Micrologix Biotech Inc.), incorporated herein by reference to the corresponding exhibit to Amendment No. 2 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on September 25, 2006
10.11 [†]	IV APAP Agreement (U.S. and Canada) dated February 21, 2006 by and between the Registrant and Bristol-Myers Squibb Company, incorporated herein by reference to the corresponding exhibit to Amendment No. 2 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on September 25, 2006
10.12 [†]	License Agreement dated December 23, 2002 by and among SCR Pharmatop and Bristol-Myers Squibb Company, incorporated herein by reference to the corresponding exhibit to Amendment No. 2 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on September 25, 2006
10.13 [†]	Loan and Security Agreement dated February 17, 2006 by and among the Registrant, Silicon Valley Bank and Oxford Finance Corporation, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006
10.15 [†]	Engagement Letter dated May 19, 2005 by and between the Registrant and Clearview Projects, Inc., incorporated herein by reference to the corresponding exhibit to Amendment No. 2 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on September 25, 2006
10.16 [†]	Amendment No. 1 dated October 6, 2006 to Collaboration and License Agreement dated July 30, 2004 by and between the Registrant and Migenix, Inc. (formerly Micrologix Biotech Inc.), incorporated herein by reference to the corresponding exhibit to Amendment No. 3 of the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on October 10, 2006

Exhibit Number	Description of Exhibit
10.17 [†]	Development and Supply Agreement by and between Cadence Pharmaceuticals, Inc. and Baxter Healthcare Corporation dated July 18, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on July 23, 2007
10.20	Second Amendment to Loan and Security Agreement dated November 30, 2007 by and among the Company and Oxford Finance Corporation, Silicon Valley Bank and Merrill Lynch Capital, a Division of Merrill Lynch Business Financial Services Inc., incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
10.24	Form of Common Stock Purchase Agreement dated February 14, 2008, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 15, 2008
10.26	Amendment No. 2 dated April 1, 2006 to Collaboration and License Agreement dated July 30, 2004 and amended as of October 6, 2006 by and between the Registrant and Migenix, Inc. (formerly Micrologix Biotech Inc.), incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended March 31, 2008 as filed with the SEC on May 9, 2008
10.27 [#]	Second Amended and Restated Cadence Pharmaceuticals, Inc. Director Compensation Policy, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2008 as filed with the SEC on November 7, 2008
10.28 [†]	Long Term Supply Agreement dated December 1, 2008 by and between Cadence Pharmaceuticals, Inc. and Solvay SA, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 5, 2008
10.29 [†]	License Agreement dated December 1, 2008 by and between Cadence Pharmaceuticals, Inc. and Solvay SA, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 5, 2008
10.30	Securities Purchase Agreement, dated February 13, 2009, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 20, 2009
10.31 ^{#±}	Form of Second Amended and Restated Employment Agreement
10.32 ^{#±}	2009 Corporate Bonus Plan
23.1 [±]	Report and 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 16, 2009

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 16, 2009
/s/ WILLIAM R. LARUE William R. LaRue	Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary (Principal Financial and Accounting Officer)	March 16, 2009
/s/ CAM L. GARNER Cam L. Garner	Chairman of the Board of Directors	March 16, 2009
/s/ BRIAN G. ATWOOD Brian G. Atwood	Director	March 16, 2009
/s/ SAMUEL L. BARKER, PH.D. Samuel L. Barker, Ph.D.	Director	March 16, 2009
/s/ MICHAEL A. BERMAN, M.D. Michael A. Berman, M.D.	Director	March 16, 2009
/s/ JAMES C. BLAIR, PH.D. James C. Blair, Ph.D.	Director	March 16, 2009
/s/ ALAN D. FRAZIER Alan D. Frazier	Director	March 16, 2009
/s/ TODD W. RICH Todd W. Rich	Director	March 16, 2009
/s/ CHRISTOPHER J. TWOMEY Christopher J. Twomey	Director	March 16, 2009

Corporate Directory

EXECUTIVE OFFICERS

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

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

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

William S. Craig, Ph.D.
Senior Vice President
Pharmaceutical Development &
Manufacturing

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

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

David A. Socks
Senior Vice President
Corporate Development & Strategy
Co-founder,
Cadence Pharmaceuticals, Inc.

Robert J. DiVasto
Vice President
Supply Operations

Catherine J. Hardalo, M.D.
Vice President
Clinical Development, Anti-Infectives

Mike A. Royal, M.D., J.D.
Vice President
Clinical Development, Analgesics

Diane K. Sheehan
Vice President
Human Resources

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.

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

Dr. Todd W. Rich
Vice President Regulatory, Medical
Information, Drug Safety, Quality and
Compliance
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

STOCK LISTING

Symbol: CADX
Stock Exchange: The Nasdaq Global
Market

CORPORATE HEADQUARTERS

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Telephone: (858) 436-1400
Facsimile: (858) 436-1401
info@cadencepharm.com

WEBSITE

www.cadencepharm.com

INVESTOR SERVICES

A copy of the company's 2008 Annual Report on Form 10-K, which is filed with the Securities and Exchange Commission, is available 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

ANNUAL MEETING

The annual stockholders meeting will be held on Wednesday, June 24, 2009 at 8:00 a.m., at the Homewood Suites by Hilton Hotel, 11025 Vista Sorrento Parkway, San Diego, California 92130

FORWARD-LOOKING STATEMENTS

This Annual Report includes forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Forward-looking statements discuss matters that are not historical facts, and include statements that include the words "believe," "expect," "anticipate," "intend," "estimate," "project," "target," "can," "could," "may," "will," "would," or similar expressions. Forward-looking statements include, but are not limited to, statements regarding our product development and commercialization plans and timetables, operating and growth strategies, cost savings initiatives, liquidity and sufficiency of our capital resources, and operating results. You should not rely on these forward looking statements, which speak only as of the date on which they were made. Our actual results may differ materially from those anticipated in these forward looking statements as a result of various factors, including, without limitation, those set forth in Item 1A, "Risk Factors," of our Annual Report on Form 10-K, dated March 16, 2009, as amended, and in our other periodic public filings with the U.S. Securities and Exchange Commission. All forward-looking statements are qualified in their entirety by this cautionary statement and we undertake no obligation to update publicly or revise such statements, whether as a result of new information, future events or otherwise, unless required by law. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.



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