UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2006

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 001-33103

CADENCE PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**41-2142317**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
12481 High Bluff Drive, Suite 200, San Diego, California	**92130**
(Address of Principal Executive Offices)	*(Zip Code)*

(858) 436-1400
(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.0001 per share	The NASDAQ Global Market

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 o No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o 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 o

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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer ☑

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes o No ☑

As of March 19, 2007, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $183,000,000, based on the closing price of the registrant's common stock on the The Nasdaq Global Market of $14.85 per share. The registrant has elected to use March 19, 2007 as the calculation date, as on June 30, 2006 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately-held concern.

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of March 19, 2007 was 29,092,720.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement to be filed with the SEC pursuant to Regulation 14A in connection with the registrant's 2007 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10- K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2006.

CADENCE PHARMACEUTICALS, INC.
FORM 10-K — ANNUAL REPORT
For the Fiscal Year Ended December 31, 2006

Table of Contents

PART I

Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, includes forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results will differ from those anticipated in these 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. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, discussions regarding our operating strategy, growth strategy, acquisition strategy, cost savings initiatives, industry, 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 IV APAP and Omigard to receive regulatory approval for one or more indications on a timely basis or at all; the results of pending clinical trials for IV APAP and Omigard; unexpected adverse side effects or inadequate therapeutic efficacy of IV APAP or Omigard that could delay or prevent regulatory approval or commercialization, or that could result in recalls or product liability claims; other difficulties or delays in development, testing, manufacturing and marketing of and obtaining regulatory approval for IV APAP or Omigard; the scope and validity of patent protection for IV APAP or Omigard; the market potential for pain, fever, local catheter site infections and other target markets, and our ability to compete; the potential to attract a strategic collaborator and terms of any related transaction; intense competititon if either of IV APAP or Omigard is ever commercialized; and our ability to raise sufficient capital when needed, or at all. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words "believes," "expects," "anticipates," "intends," "estimates," "projects," "can," "could," "may," "will," "would" or similar expressions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in 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.

Item 1. ***Business***

Overview

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 Delaware on May 26, 2004. Since our inception, we have in-licensed rights to two Phase III product candidates. We have in-licensed the exclusive U.S. and Canadian rights to IV APAP, an intravenous formulation of acetaminophen that has previously been studied in six completed Phase III trials and is currently marketed in Europe for the treatment of acute pain and fever by Bristol-Myers Squibb Company, or BMS. We believe that IV APAP is the only stable, pharmaceutically-acceptable intravenous formulation of acetaminophen. We initiated Phase III development for the treatment of acute pain in the fourth quarter of 2006 and intend to initiate Phase III development for the treatment of fever in the first half of 2007. We also in-licensed the exclusive North American and European rights to omiganan pentahydrochloride 1% aqueous gel, or Omigard™, for the prevention and treatment of device-related, surgical wound-related and burn-related infections. We are currently conducting a Phase III trial of Omigard for the prevention of local catheter site infections, or LCSI, to confirm and extend the results observed for the prevention of local catheter site infection or LCSI, a secondary endpoint, in a large, completed Phase III trial. We believe that the hospital setting is a concentrated, underserved market for pharmaceuticals and anticipate building our own, hospital-focused sales force as our products approach 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 United States or approved in the United States but with significant commercial potential for proprietary new uses or formulations.

Our current portfolio consists of the following product candidates:

- *IV APAP for the treatment of acute pain and fever.* We are developing IV APAP in the U.S. market for the treatment of acute pain and fever. According to IMS Health, Inc., or IMS, an independent marketing research

firm, over 251 million units of injectable analgesics, typically used to treat pain, were sold in the United States in 2005. Opioids such as morphine, meperdine, hydromorphone and fentanyl represent the majority of unit volume in the market but are associated with a variety of unwanted side effects including sedation, nausea, vomiting, constipation, cognitive impairment and respiratory depression. Ketorolac, a non-steroidal anti-inflammatory drug, or NSAID, is the only non-opioid injectable analgesic available for the treatment of acute pain in the United States. However, ketorolac carries strong warnings from the FDA for various side effects, including an increased risk of bleeding — a particularly troubling side-effect in the surgical setting. In March 2006, we in-licensed the patents and the exclusive development and commercialization rights to IV APAP in the United States and Canada from BMS. IV APAP has been marketed outside the United States for approximately five years. Since its introduction in Europe in mid-2002, over 200 million doses of IV APAP have been distributed, and it has become the market and unit share leader among injectable analgesics with 2006 sales in excess of $159 million. With approval in over 50 countries, the addition of IV APAP to our product pipeline is consistent with our strategy to in-license and develop pharmaceutical candidates with well-understood risk profiles. In the fourth quarter of 2006 we initiated the Phase III clinical program agreed to by the FDA at the End of Phase II meeting in August 2006. We expect the results from the Phase III clinical program to be available in the first half of 2008., If positive, we anticipate submitting a new drug application, or NDA, in the second half of 2008.

- *Omigard for the prevention of intravascular catheter-related infections.* We are developing Omigard for the prevention of intravascular catheter-related infections in the United States and Europe. According to the February 2004 *Catheter: Global Markets & Technologies* report from Theta Reports, eight million central venous catheters, or CVCs, were sold in the United States in 2003, and unit sales are projected to grow to 11 million by 2007. Although CVCs have become an important part of medical care, they can give rise to dangerous and costly complications, including: LCSIs, which are infections at the catheter insertion site; catheter colonization, which is the growth of microorganisms on the portion of the catheter below the skin surface; and catheter-related bloodstream infections, or CRBSIs, which are infections in the bloodstream caused by microorganisms associated with the catheter. The Centers for Disease Control and Prevention, or CDC, estimates that there are 250,000 CRBSIs each year in the United States. The attributable mortality rate of CRBSIs is approximately 12% to 25% with an average marginal cost to the healthcare system of $25,000 per infection. Currently, topical antiseptics are the primary agent used to prevent catheter infections, and they are used to cleanse the skin surface around the catheter insertion site prior to insertion and at dressing changes. However, the utility of these antiseptics is limited, principally due to the relatively short duration of antimicrobial activity. Omigard is a topical antimicrobial that has been demonstrated to be rapidly bactericidal and fungicidal with prolonged duration of activity against all microorganisms commonly found on the skin surface including multi-drug resistant microorganisms such as methicillin-resistant *staphylococcus aureus*, or MRSA. Importantly, resistance to Omigard has not been induced in the laboratory after extensive study nor has Omigard demonstrated potential to induce cross-resistance to other antimicrobial therapeutics. In July 2004, we in-licensed the patents and the exclusive development and commercialization rights to Omigard in North America and Europe for the prevention of device-related, surgical wound-related and burn-related infections. Omigard has previously been studied in a large, completed Phase III trial that demonstrated statistically significant outcomes for two pre-specified secondary endpoints, the prevention of LCSIs and and the prevention of catheter colonization. The presence of an LCSI may result in replacement of the catheter and/or administration of antibiotics, both of which create additional costs to hospitals and have the potential for adverse safety outcomes. In addition, catheter colonization is well correlated with CRBSIs, according to a published review of clinical trials. In August 2005, we initiated a confirmatory Phase III clinical trial with a primary endpoint, the prevention of LCSIs. We reached agreement with the FDA on the trial design, endpoints and statistical analysis plan through the special protocol assessment, or SPA, process. We expect these Phase III results to be available in the second half of 2007 and, if positive, we expect to subsequently submit an NDA for Omigard in the first half of 2008.
- *Other product candidates.* We are also exploring the opportunity to develop new formulations of omiganan pentahydrochloride for the prevention and treatment of other device-related, surgical wound-related and burn-related infections. We are currently preparing preclinical experiments in animal models prior to initiating human clinical trials.

Our Strategy

Our goal is to be 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 of and commercializing our existing product candidates. Our long-term strategy is to in-license, acquire, develop and commercialize additional product candidates that are in late-stages of development, currently commercialized outside the United States or approved in the United States but with significant commercial potential for proprietary new uses or formulations. Specifically, we intend to:

- *Obtain regulatory approval for our Phase III hospital product candidates, IV APAP and Omigard.* We are applying the expertise of our development teams to conduct and successfully complete the Phase III clinical trials associated with each product candidate. We have designed our Phase III clinical programs in an effort to reduce clinical development risk, facilitate regulatory approval and optimize marketing claims. To that end, in the fourth quarter of 2006 we resumed the U.S. Phase III program for IV APAP previously initiated by BMS, and we expect to submit an NDA in the second half of 2008 based on the trials previously completed by BMS in the U.S. and Europe and any further trials that may be required by the FDA. In addition, we have reached a written agreement with the FDA through the SPA process for a single confirmatory Phase III study of Omigard for the prevention of LCSIs.
- *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 United States. We believe that both IV APAP and Omigard can be effectively promoted by our own sales force targeting key hospitals in the United States. 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 across multiple therapeutic categories in the hospital. Outside the United States, we intend to establish strategic partnerships for the commercialization of our products 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 more fully 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 greater emphasis has shifted toward larger opportunities in the primary care 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 United States or approved in the United States 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 IV APAP, Omigard and any other product candidates we may in-license, acquire or develop by pursuing other indications and commercial opportunities for such candidates. For example, we have rights to develop and commercialize omiganan pentahydrochloride for additional indications related to the prevention and treatment of device-related, surgical wound-related and burn-related infections.

The 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 in-license, acquire, develop and commercialize 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, approximately $28 billion was spent on promotional activities by the pharmaceutical industry in 2004. 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, only 2,000 of the approximately 5,000 acute care hospitals in the United States 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 wait time in physician offices as a large number of prescribers can be found in a single location. Furthermore, drug sampling generally does not occur in hospitals, which represents a significant cost advantage versus marketing to office-based physicians. A single sales representative can promote products from multiple therapeutic categories to multiple prescribers within the institution.

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 United States. 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 United States, of which we believe most are either co-located with a hospital or located in close proximity to a hospital.

In recent years there has also been significant activity by both government agencies and accrediting organizations to hold hospitals accountable for improving patient outcomes across a wide variety of areas, including infection control, pain management, cardiovascular care and others. For example, according to the Association for Professionals in Infection Control and Epidemiology, there are now 34 U.S. states that require hospitals to publicly report their infections rates. In addition, federal legislation, the Healthy Hospitals Act, is pending which would amend the Social Security Act to require public reporting of health care-associated infection data by hospitals and ambulatory surgical centers; and it would also establish programs to provide incentives to hospitals to eliminate the rate of occurrence of such infections. These types of initiatives support our view that significant unmet medical needs remain in hospitals today.

Our Product Development Programs

Our current product development programs are focused on late-stage development products principally for use in the hospital setting. Our portfolio consists of the following product candidates:

Product Candidate	Indication	Development Stage in the United States	Development Stage in Europe	Cadence Commercial Rights
IV APAP(1)	Treatment of acute post-surgical pain — adults	Phase III	Marketed (by BMS)	United States, Canada
	Treatment of acute pain — pediatrics	Phase III	Marketed (by BMS)	United States, Canada
	Treatment of fever — adults	Phase III	Marketed (by BMS)	United States, Canada
	Treatment of fever — pediatrics	Phase III	Marketed (by BMS)	United States, Canada
Omigard	Prevention of local catheter site infections	Phase III	Phase III	North America, Europe

(1) In March 2006, we in-licensed the patents and the exclusive development and commercialization rights to IV APAP in the United States and Canada from BMS. BMS has completed Phase III trials with respect to the above indications, excluding the treatment of fever in adults, for IV APAP in Europe and the United States, which we intend to use in our NDA filing following agreement with the FDA on additional clinical trials needed in the United States for approval. Because the Phase III clinical trial requirements differ in the United States compared to Europe, we are required to complete additional Phase III trials, particularly to demonstrate safety and efficacy from multiple day dosing in additional patient populations, including patients undergoing soft tissue surgery, such as abdominal hysterectomy, and patients with fever. In the fourth quarter of 2006, we initiated the remaining Phase III clinical trial requirements for submission in the United States. We expect the Phase III clinical trial results to be available in the first half of 2008 and, if positive, to submit an NDA in the second half of 2008.

IV APAP for the Treatment of Acute Pain and Fever

Acute Pain Background

Acute pain is generally defined as pain with relatively short duration and recent onset with an easily identifiable cause. It serves to warn the patient of tissue damage and is often sharp initially and followed by aching pain. In the hospital setting, acute pain is generally classified as post-operative or non-operative.

Post-operative pain is a response to tissue damage during surgery that stimulates peripheral nerves, which signal the brain to produce a sensory and emotional response. Post-operative pain may occur not only at the surgical site but also in areas not directly affected by the surgical procedure. The pain may be experienced by an inpatient or outpatient and can be felt after surgical procedures.

Numerous studies reveal that the incidence and severity of post-operative pain is primarily determined by the type of surgery, duration of surgery and the treatment choice following surgery. Post-operative pain is usually greatest with abdominal, head-neck, orthopedic and thoracic surgery and may last up to eight days after the surgical procedure. In comparison, surgical procedures such as arthroscopy, breast biopsy, hernia repair and plastic surgery tend to be less invasive and generally produce minor surgical trauma.

Despite major improvements in surgical techniques and the introduction of novel drugs, the overall treatment of post-operative pain has not substantially improved over the last 20 years. According to the industry research group Datamonitor, up to 75% of patients report inadequate pain relief. Such inadequate pain relief often leads to nausea, vomiting, decreased mobilization and reduced nutritional intake — all of which impede patient recovery —

and can lead to infections and blood clots in the legs and lungs — all of which jeopardize patient safety. All of these factors have a major impact on patient care and hospital economic outcomes, including prolonged hospital stays.

Non-operative pain in the hospital is typically associated with diseases, disorders, trauma and other conditions. The most common non-operative pain types among hospitalized patients include pain associated with cancer, trauma, burns, gallstones and cardiovascular events. Other incidences of non-operative pain among hospitalized patients are often related to HIV, pancreatitis, sickle cell disease and other diseases. Inadequate pain management in these patients also leads to poor health and economic outcomes.

Market for Injectable Analgesics

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, faster onset of analgesia is required, or it is otherwise more convenient to administer drugs in injectable form. Hospitalized patients may be unable to take medications by mouth for a variety of reasons including post-anesthesia sedation, other forms of sedation, nausea, vomiting, gastrointestinal limitations or other conditions.

According to IMS, the U.S. market for injectable analgesics exceeded 277 million vials in 2006. Morphine is the current market leader and accounted for more than 148 million vials in 2006. Other injectable opioids such as meperidine, hydromorphone and fentanyl, which are all available in generic forms, accounted for more than 94 million vials in 2006. Ketorolac (Toradol), a genericized NSAID, is the only non-opioid injectable analgesic for acute pain available in the United States. According to IMS, injectable ketorolac sold more than 34 million vials in 2006.

According to Datamonitor, up to 53 million patients undergo surgical procedures each year in the United States. Datamonitor projects the number of surgical procedures to increase as the elderly population increases and as technological advances allow new surgical procedures to be performed. As such, we expect that the need for safe and effective drugs to treat pain in the post-operative setting will continue to increase.

Limitations of Current Therapies

Only two classes of injectable analgesics, opioids and NSAIDs, are currently available in the United States 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 activate certain receptors in the central nervous system, which produce analgesia, euphoria and other positive effects. A range of opioids are available in injectable form including morphine, fentanyl, meperidine and hydromorphone.

Opioids, however, are associated with a variety of unwanted side effects including sedation, nausea, vomiting, constipation, headache, cognitive impairment and respiratory depression. Respiratory depression can lead to death if not monitored closely. Side effects from opioids have been demonstrated to reduce quality of life and side-effect-related dosing limitations can result in suboptimal pain relief due to under-dosing. All of these side effects may require additional medications or treatments and can prolong patient stay in the post-anesthesia care unit as well as a patient's overall stay in the hospital or in an ambulatory surgical center.

Opioid-related side effects also impose significant economic burdens on hospitals and ambulatory surgical centers. For example, nausea and vomiting, common opioid-related side effects, can cause the need for administration of anti-nausea medication, increased monitoring by nurses, increased length of stay in the post-anesthesia care unit and overall length of stay in the hospital, diverting resources that could otherwise be utilized in revenue-generating activities. Studies have demonstrated increased costs related to post-operative opioid administration from not only increased personnel time and length of stay but also increased supply and drug costs, including drugs to manage the nausea and vomiting.

The only non-opioid intravenous analgesic for acute pain available in the United States 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 to opioids for the relief of acute pain. Studies have also demonstrated the opioid-sparing potential of ketorolac when used in combination with opioids, as well as resulting decreases in hospital costs. Published studies have shown lower overall per-patient costs ranging from $326 to $2,031 for the patients treated with ketorolac and opioids compared to those treated with opioids alone.

Despite these economic advantages, the use of ketorolac is severely limited in the post-operative period. Non-specific NSAIDs such as ketorolac block COX-1, which plays a major role in the release of prostaglandins to regulate platelet aggregation and protect the lining of the stomach. As a result, bleeding, gastrointestinal and renal complications are significant impediments to the post-operative use of ketorolac. The product carries a black box warning for these 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 warning prescribers about adverse drug reactions that can cause serious injury or death. The FDA specifically warns that ketorolac should not be used in various patient populations that are at-risk for bleeding, as a prophylactic analgesic prior to major surgery or for intraoperative administration when stoppage of bleeding is critical.

The World Health Organization, or WHO, has established a three-step analgesic ladder for the treatment of pain, which recommends initial treatment with a non-opioid such as acetaminophen, aspirin, or NSAIDs followed by the addition of opioids as pain increases. The WHO analgesic ladder is consistent with the practice of multimodal analgesia, which involves the use of more than one class of drug for pain control to obtain additional analgesia, reduce side effects or both. In the United States, this recommended practice of multimodal analgesia is not fully available to physicians given the current lack of an intravenous formulation of acetaminophen. With the availability of IV APAP in Europe, physicians are able to treat post-operative pain with IV APAP as baseline therapy and use opioids in combination as needed for increasing levels of pain.

Fever

Fever is an increase in internal body temperature above its average normal value of 98.6± 0.7 degrees Fahrenheit (37±0.4 degrees Centigrade). A significant fever is usually defined as an oral temperature of greater than 101.5 degrees Fahrenheit (38 degrees Centrigrade) or a rectal or ear (tympanic membrane) temperature of greater than 103 degrees Fahrenheit (39.5 degrees Centigrade). Oral temperature is usually 0.5 degrees Fahrenheit (0.3 degrees Centigrade) below core temperature (e.g., as assessed via the rectum or tympanic membrane). 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 given the potential exposure to various infectious microorganisms, invasive procedures and medications. Surgery is the most common source of fever in the hospital setting, and published incidence rates range from 14% to 91% of post-operative patients. Infections such as wound infections, urinary tract infections and pneumonia are the next most frequent causes. However, deep venous thrombosis, pulmonary emboli, myocardial infarction and medications are also important potential sources of fever. Many patients also present with fever upon arrival at the hospital due to community-acquired infections, underlying diseases, including cancer and HIV, severe sunburn, and often, the origin of a fever is unknown.

Fever is also the most common reason parents bring their children to the emergency rooms of hospitals. Pediatric fever is particularly worrisome as approximately 4% of children under age five and nearly one in five children who were preterm at birth 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 medications to treat fever. The use of ibuprofen, an NSAID, and aspirin are limited due to gastrointestinal side-effects and the risk of bleeding. Ibuprofen is not approved for children under six months of age and is not recommended for patients that 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.

In the United States, acetaminophen, ibuprofen and aspirin are not available in intravenous dosage form. However, oral delivery of medications is often not possible for hospitalized patients that are unconscious, sedated, fasting, experiencing nausea and vomiting or are otherwise unable to take medications by mouth. Rectal delivery of medications is sometimes possible; however, drug absorption is often erratic, resulting in unpredictable levels of efficacy. Rectal delivery in infants is further complicated by frequent bowel movements which may lead to difficulty determining the amount of medication delivered. It is often more convenient to administer medications in intravenous dosage form, particularly for patients that currently have an intravenous line in place. We believe that the availability of IV APAP in the United States would offer a significant new treatment option for hospitalized patients with fever.

IV APAP

IV APAP has been marketed by BMS in Europe since its launch in France in mid-2002 and subsequent approvals in other countries throughout Europe and other parts of the world. After obtaining these approvals, BMS elected to seek a partner to develop and commercialize IV APAP in the United States and Canada based on a new corporate strategy to focus the company's research and development on 10 specific disease areas, which do not include the treatment of pain. In March 2006, we completed our agreement with BMS to in-license these rights.

Acetaminophen is the most widely used drug for pain relief and the reduction of fever in the United States. The mechanism of action of acetaminophen remains not well understood; however, it is believed that acetaminophen acts in part on central COX enzymes without the peripheral anti-inflammatory effects, platelet inhibition or other side effects associated with NSAIDs. Acetaminophen was discovered in the late 19th century but was not available for sale until 1955 when it was introduced under the brand name Tylenol in the United States. 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.

Historically, poor stability in aqueous solutions and inadequate solubility of acetaminophen prevented the development of an intravenous dosage form. Acetaminophen will decompose in the presence of oxygen and water. The rate of decomposition is accelerated as the temperature is increased and upon exposure to light. The stability is also a function of the solution's pH, which creates a further challenge to formulate acetaminophen in an aqueous solution suitable for intravenous administration. We believe that IV APAP is the only stable, pharmaceutically-acceptable intravenous formulation of acetaminophen. Inactive ingredients, or excipients, in the formulation protect acetaminophen from destabilization by oxygen in the solution.

Prior to the introduction of IV APAP in Europe, BMS had developed an intravenous formulation of propacetamol, a prodrug that is rapidly converted in the bloodstream to acetaminophen. This formulation was developed as an alternative approach given the challenges associated with formulating acetaminophen itself in solution. Available in Europe for more than 20 years, intravenous propacetamol was marketed under the brand name Pro-Dafalgan and was generally indicated for the treatment of acute moderate pain and the reduction of fever. Pro-Dafalgan was provided for use as a dried powder to be reconstituted in solution prior to intravenous administration. In healthcare workers reconstituting the drug, there were reported incidences of allergic reactions, including mild allergic reactions on the skin and severe allergic shock from inhalation. Intravenous propacetamol was also associated with pain at the injection site and other local reactions in approximately 50% of patients receiving the drug.

IV APAP was approved in Europe based on clinical data demonstrating that the formulation provides superior analgesic efficacy over placebo and similar analgesic efficacy and bioequivalence to intravenous propacetamol. Well-controlled clinical trials have demonstrated that IV APAP has a safety profile similar to placebo with significantly better tolerability than intravenous propacetamol upon infusion. Pain at the injection site has been demonstrated to be no different than placebo.

IV APAP is the only intravenous formulation of acetaminophen available anywhere in the world and has now been approved in over 50 countries. BMS markets IV APAP in Europe and other countries principally under the brand name Perfalgan. When BMS launched IV APAP, it withdrew intravenous propacetamol from the market. Two strengths of IV APAP are commercially available in these countries in a ready-to-use solution: a 50mL bottle

containing 0.5g acetaminophen and a 100mL bottle containing 1g acetaminophen. Both are labeled for administration via a 15-minute intravenous infusion.

In Europe, IV APAP was initially launched in France in mid-2002, followed by Germany and Spain in 2003 and Italy and the United Kingdom in 2004. Despite this country-by-country launch, IV APAP achieved a 44% dollar share (20% vial share) as of the fourth quarter of 2006. In 2006, IV APAP sold more than 64 million vials, which represents a 17% increase over 2005. Total sales of IV APAP exceeded $159 million (U.S. dollars) in 2006 according to IMS.

We believe the United States represents a substantially larger market opportunity for IV APAP than Europe with respect to the number of surgical procedures and potential pricing. For example, the United States accounts for nearly 50% of worldwide hip and knee replacement surgeries; whereas, Europe only accounts for approximately 30% of such surgeries, according to Datamonitor. More significantly, pharmaceutical pricing continues to be higher in the United States on average. Each country in the European Union currently employs direct and other forms of price controls, including reference systems where prices for new drugs are based upon the prices of existing drugs that provide similar therapeutic benefit or prices of drugs in other European countries. According to IMS, the average selling price in Europe was approximately $2.50 (U.S. dollars) per vial of IV APAP. In contrast, the price of Toradol (ketorolac) in the United States 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 adoption include the proven efficacy and established safety profile of acetaminophen, the potential ability to reduce concomitant use of morphine and other opioids, a more convenient dosage form for some patients and a more rapid onset of action.

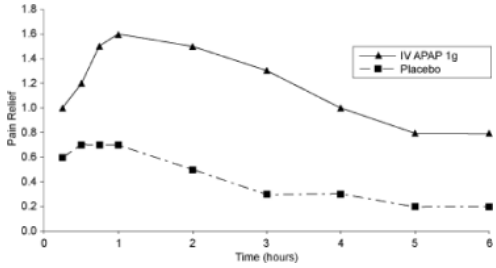
Clinical Development History

Clinical Overview. There have been 2,241 subjects, including 1,780 subjects that received IV APAP, studied in nine clinical trials completed by BMS, largely submitted to support the Marketing Authorization Application, or MAA, that resulted in European approval. These trials included two Phase I trials, six Phase III trials and one large Phase IV trial. Overall, we believe that the results of these nine studies demonstrate that IV APAP is safe and effective in the treatment of post-operative pain in adults and children. These trials have also demonstrated that IV APAP reduces the consumption of opioids when used in combination.

Clinical Studies for Post-Operative Pain in Adults. One Phase III study evaluated 152 adult subjects with moderate-to-severe pain following total hip and total knee replacements. Subjects were randomized to receive IV APAP, intravenous propacetamol or placebo. We believe this study best demonstrates the efficacy of IV APAP since the patients in the trial were undergoing surgical procedures with more severe levels of pain. On the primary efficacy endpoint, pain relief scores in the patients treated with IV APAP were statistically higher (*p-value*< 0.05) than those treated with placebo and not statistically different than those treated with intravenous propacetamol from 15 minutes to six hours, at which point patients received a second dose.

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.

The following graph presents the results for pain relief reported by patients in this Phase III study for post-operative pain in adults following major orthopedic surgery, based on a five point verbal scale, with four representing complete pain relief and zero representing no pain relief:



In addition, this Phase III study demonstrated the following results:

Outcome Measure	Result	p-value
Median time to morphine rescue	3.0 hours for IV APAP vs. 0.8 hours for placebo	<0.001
Reduction in morphine consumption over the 24-hour period	33% reduction (19.1mg) for IV APAP compared to placebo	<0.01

This Phase III study also demonstrated a statistically significant reduction in pain intensity and a statistically significant improvement in patient satisfaction with pain treatment for IV APAP compared to placebo (with nearly twice as many subjects noting good or excellent results at 24 hours compared with placebo despite using one third less morphine). Drug-related adverse events in this trial were similar to placebo.

Two Phase III studies evaluated a total of 349 adult subjects with moderate-to-severe pain following third molar surgery. Subjects were randomized to receive IV APAP, intravenous propacetamol or placebo. Statistically significant effects versus placebo (*p-value*< 0.01) were obtained with IV APAP for all efficacy criteria, including pain relief, pain intensity difference, duration of analgesia and patients' global evaluation. There were no statistically significant differences in treatment-related adverse events between IV APAP and placebo. IV APAP demonstrated similar results on all efficacy parameters compared to intravenous propacetamol with significantly lower incidence of pain at the injection site.

One Phase III study evaluated 163 adult subjects with moderate-to-severe pain following minor gynecologic surgery. Subjects were randomized to receive IV APAP or intravenous propacetamol. IV APAP demonstrated similar results on all efficacy parameters compared to intravenous propacetamol with statistically significantly lower incidence of pain at the injection site.

One Phase IV study evaluated 1,061 subjects with mild-to-moderate pain following surgery. All subjects received up to four doses of IV APAP over a 24-hour period. This trial provided additional data regarding the administration of multiple-doses of IV APAP.

Clinical Studies for Post-Operative Pain in Children. One Phase III study evaluated 183 pediatric subjects with moderate-to-severe pain following surgery for hernia repair. Subjects were randomized to receive IV APAP or intravenous propacetamol. IV APAP demonstrated similar results on all efficacy parameters compared to intravenous propacetamol with significantly lower incidence of pain at the injection site.

Clinical Studies for Fever in Children. One Phase III study evaluated 67 pediatric subjects (age one month to 12 years) with fever of infectious origin. Subjects were randomized to receive IV APAP or intravenous propacetamol. IV APAP demonstrated similar results on all efficacy parameters compared to intravenous propacetamol with statistically significantly lower incidence of pain at the injection site.

Safety Summary. The safety of acetaminophen has been well-established through decades of use in oral, suppository and intravenous formulations. The primary safety concern with acetaminophen is hepatotoxicity, which is a well-understood and dose dependent, rarely occurring 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 there is no evidence that IV APAP poses an increased risk for hepatoxicity or any other adverse event. In fact, in the 1,780 subjects receiving IV APAP in nine clinical trials previously completed by BMS, the product has exhibited a safety profile consistent with published data for oral acetaminophen. Additionally, in placebo-controlled trials, IV APAP was associated with fewer hepatic events than placebo, although this difference was not statistically significant. This is also consistent with observations from the European post-marketing safety database of IV APAP which covers a time period in which over 200 million doses were administered to patients.

In pharmacokinetic trials, the peak plasma concentration of acetaminophen ranged from 50% to 74% higher for IV APAP compared to oral acetaminophen; however, total plasma concentrations over time were not meaningfully different. Further, these results demonstrated that urinary elimination of acetaminophen metabolites, including metabolites with potential to interact with the liver, was not meaningfully different for IV APAP compared to oral acetaminophen at 12 and 24 hour measurements. Therefore, the study concluded that IV APAP 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.

Opioid Sparing Summary. The use of IV APAP in clinical trials has consistently been associated with at least a 33% reduction in opioid consumption compared to placebo. In these cases, opioids were available at the discretion of patients utilizing patient controlled analgesia, or PCA, devices.

Clinical Development Plan

We are developing IV APAP based on a targeted indication for the treatment of acute pain, usually in the post-operative setting, and the treatment of fever. We are seeking approval for use in both adults and children for these indications. Our proposed development plan to support this indication integrates the existing body of intravenous propacetamol data, IV APAP data and the data generated by clinical studies of IV APAP to be conducted by us. Under our agreement with BMS, we have rights to reference these BMS data. We intend to submit a 505(b)(2) NDA for IV APAP based on these data sets as well as references to the extensive literature which supports the safety and efficacy of acetaminophen in oral formulations. 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.

In August 2006, we met with the FDA to discuss the clinical trial requirements for submission of a 505(b)(2) NDA for IV APAP. Based on the feedback from the FDA, we intend to conduct six clinical trials to provide the FDA with additional data to support multiple dose efficacy for soft tissue surgery, efficacy for fever and safety in adults and children. These trials include:

- Phase III trial in female patients with moderate-to-severe pain following gynecologic surgery: this trial will be a randomized, placebo-controlled, double-blind, multi-center study to assess the efficacy and safety of single and multiple doses of IV APAP.
- Phase III trial in adults with fever: this trial will be a randomized, controlled, double-blind, double-dummy study to assess the efficacy and safety of a single dose of IV or oral APAP vs. placebo.
- Pharmacokinetic study in adult subjects: this trial will be a randomized, single-center study to assess the pharmacokinetics of single and multiple doses of IV APAP compared to oral acetaminophen in adults. This trial was fully enrolled in December 2006 and we expect data to be available in the first half of 2007.

- Pharmacokinetic study in pediatric subjects: this trial will be a randomized, single-center study to assess the population pharmacokinetics of single and multiple doses of IV APAP compared to oral acetaminophen in children.
- Safety study in adult subjects: this trial will be an open-label, multi-center, multi-day study to assess the safety of repeated doses of IV APAP over at least 5 days in at least 50 adults.
- Safety study in pediatric subjects: this trial will be an open-label, multi-center, multi-day study to assess the safety of repeated doses of IV APAP over at least 5 days in at least 50 children.

Total enrollment of the six clinical trials is expected to be approximately 750 subjects. We initiated the gynecologic surgery Phase III trial and completed enrollment of the adult pharmacokinetic study in the fourth quarter of 2006. We intend to initiate the other clinical trials in the first half of 2007. In addition, BMS is conducting a randomized trial in patients undergoing hip replacement surgery. We expect the data from this trial to be available to us in 2007.

Omigard for the Prevention of Intravascular Catheter-Related Infections

Intravascular Catheter-Related Infections Background

The use of catheters for vascular access has become essential to medical practice. Intravascular catheters are inserted through the skin and advanced so that the tip rests in a vein or artery. Intravascular catheters are typically classified as either peripheral lines which access smaller veins or central lines (such as CVCs, peripherally inserted central catheters and arterial lines) to access larger veins (such as the jugular, femoral and subclavian veins) and arteries. Although such catheters provide necessary access to veins and arteries, their use puts patients at risk for dangerous and costly complications, including LCSIs, catheter colonization and CRBSIs, and, to a lesser degree, infections in other organs including the heart, lungs, brain and bones.

Based on published clinical studies, we estimate that, of patients with a CVC, approximately 10% will develop an LCSI and 20% will develop catheter colonization. This translates into approximately one million LCSIs and two million incidences of catheter colonization in the United States each year. The presence of an LSCI may result in replacement of the catheter and/or administration of antibiotics, both of which create additional costs to hospitals and have the potential for adverse safety outcomes. In addition, catheter colonization is well correlated with CRBSIs, according to a published review of clinical trials.

The CDC estimates that there are more than 250,000 CRBSIs among hospitalized patients and more than 75,000 CRBSIs among hemodialysis patients in the United States each year. Attributable mortality is estimated by the CDC to be 12% to 25% for each CRBSI, which translates into 39,000 to 81,250 deaths annually due to CRBSIs. Further, the CDC estimates that the average cost per infection is estimated to be $25,000 and, for patients in the intensive care unit, is estimated to be up to $56,000.

The additional costs related to infectious complications from CVCs result in an estimated annual burden to the healthcare system exceeding $6 billion. The majority of these costs are shouldered by hospitals due to the reimbursement system. Adopted by Medicare in 1983, the Prospective Payment System for acute hospital inpatient services generally establishes pre-determined reimbursement amounts, or diagnosis-related groups, which are classifications based on the patient's discharge diagnoses, procedures performed and other patient factors. Similar prospective payment systems were later adopted for certain other Medicare inpatient hospital services, such as rehabilitation and psychiatric hospitals. When the costs of treating a patient fall below or are above these prospective payment amounts, the hospital reaps the respective benefit or bears the respective cost. Therefore, there is a compelling economic incentive for these hospitals to use all available means to reduce infections.

The CDC estimates that hospital-acquired bloodstream infections are the eighth leading cause of death in the United States and that intravascular catheters are the leading cause of hospital-acquired bloodstream infections. Furthermore, a recent study in the New England Journal of Medicine reported that 70% of these infections are antibiotic-resistant, making them more difficult and costly to treat. Consumer groups, the CDC and the Joint Commission on Accreditation of Healthcare Organizations, or JCAHO, are calling for greater scrutiny and wider reporting of data on hospital-acquired infections. JCAHO or other recognized accreditation is necessary for

reimbursement eligibility with Medicare and most insurers. Laws have been passed mandating public reporting of hospital-acquired infection data in 34 U.S. states including Washington, Oregon, California, Nevada, Utah, Wyoming, Colorado, New Mexico, Texas, Nebraska, Kansas, Minnesota, Missouri, Arkansas, Illinois, Tennessee, Mississippi, Michigan, Indiana, Ohio, Florida, Georgia, South Carolina, West Virginia, Virginia, Pennsylvania, New York, Vermont, New Hampshire, Rhode Island, Connecticut, New Jersey, Delaware, and Maryland. In addition, federal legislation, the Healthy Hospitals Act, is pending which would amend the Social Security Act to require public reporting of health care-associated infection data by hospitals and ambulatory surgical centers and it would also establish programs to provide incentives to hospitals to eliminate the rate of occurrence of such infections. These types of initiatives support our view that significant unmet needs remain in hospitals today.

Market for Antimicrobials to Prevent Intravascular Catheter Infections

Theta Reports estimates that nearly 500 million intravascular catheters will be used in the United States in 2006, including approximately 10 million CVCs. Unit sales of CVCs are projected to grow at 9% per year. Outside the United States, Theta Reports estimates that approximately 11 million CVCs will be used in 2006. The number of CVC placements is increasing as the population continues to age and hospitalized patients become increasingly compromised. We estimate that patients with a CVC receive, on average, three to four topical antiseptic or antimicrobial applications during a hospital stay. This translates into more than an estimated 30 million applications in the United States in 2006 for CVCs alone.

The Centers for Medicare and Medicaid Services indicate that there were more than 321,500 patients with end-stage renal disease receiving dialysis at the end of 2004, of which approximately 25% had a CVC. This patient population has been growing at an annual rate of approximately 8% due to the aging population, rise in diabetes, shortage of organ donors and improved technologies enabling longer survival of patients with end-stage renal disease. Patients on hemodialysis receive, on average, three topical antiseptic or antimicrobial applications per week. This translates into more than an estimated 12 million applications in the United States in 2006.

The use of topical antimicrobials to prevent infections associated with other central lines, including arterial lines and peripherally inserted central catheters, also represents a significant market opportunity. According to Theta Reports, there are more than 2 million peripherally inserted central catheters inserted in the United States each year. We estimate there are also approximately 7 million arterials lines inserted in the United States each year.

Limitations of Current Therapies

Microorganisms on the skin surface have been demonstrated to be the leading cause of intravascular device-related infections, including LCSIs and CRBSIs. The same microorganisms on the skin that cause LCSIs can lead to CRBSIs. Given the evidence for the importance of killing microorganisms on the skin surface to prevent the development of intravascular device-related infections, the use of topical antimicrobials is critical. However, currently available products have significant limitations.

The standard of care for skin antisepsis prior to catheter insertion and at dressing changes has been dominated by either povidone-iodine, also known as Betadine, or chlorhexidine, although usage patterns, particularly in the U.S. are increasingly favoring chlorhexidine. In 2002, the CDC published guidelines that stated that although chlorhexidine is preferred, povidone-iodine can be used. In 2002, a meta-analysis of eight heterogeneous studies comparing various formulations of chlorhexidine to povidone-iodine for the prevention of catheter-related infections was published. While the meta-analysis indicated a benefit to chlorhexidine, only one of the eight studies on its own demonstrated a statistically significant prevention of CRBSIs. We believe that this change in medical practice despite the lack of robust clinical evidence underscores the desire and willingness of healthcare providers to address this significant unmet need.

Although topical antiseptics tend to have a broad spectrum of antimicrobial activity, duration of activity ranges from minutes to hours after application. These products do not provide sustained antimicrobial coverage throughout the periods between dressing changes (typically every 72-96 hours), and this lack of sustained antimicrobial activity can put patients at increased risk for acquiring an infection at the catheter insertion site.

In order to address the limited duration of activity associated with topical antiseptics, topical antibiotics have been used, either alone or in combination with topical antiseptics, to confer protection against microbial invasion. Clinical trials have shown benefits attributable to topical antibiotics, but these products have either been associated with increased frequency of fungal infections or emergence of bacterial resistance, including MRSA. These drawbacks have significantly diminished the use of topical antibiotics for the prevention of catheter-related infections. As a result, the market has almost exclusively switched back to the use of topical antiseptics.

There is some limited use of BioPatch, a chlorhexidine-impregnated foam dressing that is placed around the catheter at the insertion site. While this product retains chlorhexidine at the catheter insertion site over a period of days, it has not been widely adopted, reportedly due to difficulty in applying the dressing and the inability to visibly inspect the insertion site through the dressing. Physicians and nurses must lift up the BioPatch to monitor the insertion site for redness, swelling and other leading signs of infection. Such disruption of the dressing has the potential to interfere with the sterility of the site and promote the spread of pathogens.

Other products either in use or in development to reduce catheter-related infections are focused on downstream aspects of the infectious process. Some catheters coated with antiseptics and antibiotics have demonstrated reductions in catheter-related infections. Other new technologies being developed include contamination-resistant hubs, attachable cuffs, new catheter-coatings and antiseptic catheter lock solutions. We believe any use of these products would be in addition to the use of antimicrobial agents on the skin surface to prevent catheter-related infections.

Omigard

Omigard was discovered by researchers at Migenix. Migenix subsequently entered into a collaboration and license agreement with Fujisawa Healthcare, Inc., or Fujisawa. In that agreement, Fujisawa was granted the rights to commercialize Omigard in North America in return for licensing payments, funding of all remaining development costs and establishment of a joint development committee. In January 2004, Migenix reacquired all rights to Omigard from Fujisawa after completion of the first Phase III trial and then, in July 2004, licensed both the North American and European rights to us with the objective of completing the development program and commercializing the product.

Unlike other topical antimicrobials, Omigard exhibits a combination of features that we believe make it an ideal product for the prevention of catheter-related infections. Such features include:

- broad spectrum bactericidal and fungicidal activity;
- activity against resistant strains, including MRSA and vancomycin resistant enterococci, or VRE;
- rapid and prolonged duration of effect;
- resistance to Omigard has not been induced in the laboratory;
- no demonstrated ability to generate cross-resistance to other antimicrobials;
- excellent safety profile; and
- convenient application.

Omigard is effective against a wide variety of bacteria and fungi. The compound has been tested against more than 285 strains of Gram-positive and Gram-negative bacteria as well as more than 75 fungal strains. These studies demonstrate that Omigard has broad bactericidal and fungicidal activity against bacteria and fungi commonly found on the surface of human skin. Further, Omigard has also demonstrated the ability to kill multi-drug resistant microorganisms, including MRSA, and VRE. The incidence of resistant infections is increasing, and these microorganisms represent a potentially significant threat to the public health.

Omigard has demonstrated not only the ability to kill rapidly but also, unlike the topical antiseptics, a prolonged duration of effect. In preclinical studies with Omigard, most microorganisms were killed after only six minutes of exposure. In skin surface studies, Omigard demonstrated the ability to kill more than 99.9% of microorganisms for at least three days.

In laboratory testing conducted by Migenix, resistance to Omigard, unlike antibiotics, has not been demonstrated, nor has cross-resistance to other antimicrobials been demonstrated. A primary mechanism of action of Omigard is believed to be depolarization of the outer cell membrane of infectious microorganisms, resulting in cell death. Specific chiral receptors within the cell have not been shown to be involved in the disruption of the cell membrane and, therefore, this non-specific mechanism of action decreases the likelihood of the development of resistance.

Omigard presents a benign toxicological profile when administered topically at doses as much as 30 times the planned human dose. The product has been demonstrated to be non-irritating to the skin, non-sensitizing to the skin, and to not be absorbed through the skin into the bloodstream (based on the inability to detect Omigard in the bloodstream at very low levels) and, therefore, has no meaningful systemic exposure.

Omigard is packaged in a convenient, single unit-of-use plastic squeeze vial. Omigard, which is formulated as a 1% clear viscous, aqueous gel, is applied around the catheter insertion site by squeezing the plastic vial. Unlike the topical antiseptics, Omigard does not have to be scrubbed onto the skin surface. Unlike povidone-iodine, Omigard does not have the potential to stain the skin and clothes of patients and healthcare providers.

Clinical Development History

Migenix completed one Phase I and two Phase II studies of Omigard that treated 273 subjects. These trials demonstrated no evidence of skin sensitization, clinically significant skin irritation, or any measurable systemic absorption. In addition, the Phase I trial exhibited killing of greater than 99.9% of organisms on skin and maintained this level of antimicrobial activity for at least three days.

Migenix (then known as Micrologix) and Fujisawa subsequently completed a multi-center, randomized, evaluation committee-blinded Phase III trial that compared Omigard to 10% povidone-iodine in patients receiving CVCs, peripherally inserted central catheters, and/or arterial lines. The study was conducted in 1,407 patients in 27 centers in the United States. The primary efficacy endpoint was to demonstrate the superiority of Omigard over 10% povidone-iodine for the prevention of CRBSIs, as determined by a treatment-blinded evaluation committee. Secondary efficacy endpoints included demonstrating the superiority of Omigard for the prevention of LCSI and catheter colonization.

Treatment with Omigard resulted in the statistically significant prevention of catheter colonization compared to 10% povidone-iodine (*p-value* =0.002). The Omigard group had 21.9% fewer incidences of catheter colonization than the 10% povidone-iodine group.

	Treatment Arm		
Variable	**10% povidone-iodine**	**Omigard**	**p-value**
Catheter colonization present	232/583 (39.8)%	180/578 (31.1)%	0.002

Treatment with Omigard also resulted in the statistically significant prevention of LCSI (*p-value*=0.004). The table below summarizes data for LCSI in the modified intent-to-treat analysis set, which includes all treated patients who did not have a bloodstream infection present at baseline. As shown in the table, the Omigard group had 49.2% fewer LCSIs than the 10% povidone-iodine group. Moreover, there was a greater than 50% reduction in the number of patients that had a catheter removed because of suspected local infection (*p-value* =0.002).

	Treatment Arm		
Variable	**10% povidone-iodine**	**Omigard**	**p-value**
LCSI present	48/699 (6.9)%	24/693 (3.5)%	0.004

The study did not show statistical significance for the primary endpoint: the prevention of CRBSI. The table below compares the incidence of CRBSI in the modified intent-to-treat analysis set after treatment with Omigard or 10% povidone-iodine. The rates of failure (development of CRBSI) and indeterminate response were similar for the two treatments arms. There was a 15.4% reduction in the incidence of microbiologically-proven CRBSI in the Omigard group compared to 10% povidone iodine; however, this outcome was not statistically significant.

Outcome	Treatment Arm		p-value
	10% povidone-iodine	Omigard	
Failure	18/699 (2.6)%	15/693 (2.2)%	0.622
Success	635/699 (90.8)%	630/693 (90.9)%	
Indeterminate	46/699 (6.6)%	48/693 (6.9)%	

The definition of CRBSI required an organism isolated from a peripheral blood draw to be microbiologically or genotypically matched to an organism isolated from the catheter tip. In this study, many catheters were lost and the organisms could be not isolated from the catheter tip. Similarly, many patients were administered systemic antibiotics for suspected bloodstream infections but were given such antibiotics prior to taking a blood draw. As a result, a very high rate of indeterminate CRBSI determinations was observed (75%), which we believe was a significant factor contributing to the lower than expected rate of CRBSI. In addition, the study enrolled a large number of patients that were at relatively low risk for developing a CRBSI, which we believe further decreased the event rate to a point where, as observed, a statistically significant difference for CRBSI between the two treatment arms could not be detected. We believe that the CRBSI endpoint, as defined in the previous study, is not achievable without a very significant increase in the number of patients enrolled.

Omigard had an excellent safety profile in this study. Only 14 patients (2.0%) in each treatment group had adverse events that were considered drug-related. All of these Omigard adverse events were related to the catheter insertion site, and none were serious. Overall, there were no statistically significant differences between the treatment groups for any safety variable.

Clinical Development Plan

In June 2005, we reached agreement on the clinical development plan for Omigard with the FDA under the FDA's SPA process. The SPA process provides for a formal review and written agreement of clinical protocols that are binding on both the FDA and the company sponsor. Through the SPA process, the FDA agreed that a single confirmatory Phase III trial would be required for approval of Omigard and that LCSI would be the sole primary efficacy endpoint. Secondary endpoints include catheter colonization and other measures of infection.

The presence of an LCSI will typically result in one of several actions being taken by a physician, including administration of systemic or topical antimicrobials and/or removal and replacement of the catheter. The most serious risks from catheter replacement include bleeding from a damaged artery or puncturing of a lung. Further, the same microorganisms on the skin surface that cause LCSIs can cause CRBSIs. A published review of clinical trials found that catheter colonization is well correlated to CRBSIs.

We have completed a market research study that indicates physicians only modestly favor (73% vs. 65%) a profile of Omigard that demonstrates a statistically significant prevention in LCSIs, catheter colonization and CRBSIs compared to a profile of Omigard that demonstrates a statistically significant prevention in LCSIs and catheter colonization alone. The FDA has communicated to us that LCSI is a clinically relevant indication and, based on these market research findings, we believe that a product indicated for the prevention of LCSIs is also a highly relevant indication to physicians.

The confirmatory Phase III trial that we are conducting according to the SPA, known as the Central Line Infection Reduction Study, or CLIRS trial, is a multi-center, randomized, evaluation committee-blinded study in patients receiving a CVC. The primary efficacy endpoint of the study is to evaluate whether Omigard is superior to 10% povidone-iodine in the prevention of LCSI in patients requiring central venous catheterization. Secondary objectives of the study are to evaluate whether Omigard is superior to 10% povidone-iodine treatment in preventing significant catheter colonization, CRBSI and all-cause bloodstream infections in patients requiring central venous catheterization.

The CLIRS trial is designed to recruit 1,250 patients randomized to receive either Omigard or 10% povidone-iodine. The study began enrollment in August 2005 and is currently being conducted at centers in the United States and Europe. We expect to complete enrollment and have results available in the second half of 2007. The Omigard development program holds fast track status from the FDA, and Cadence intends to submit an NDA to the FDA in the first half of 2008.

We also intend to submit an MAA to European regulatory authorities in the first half of 2008. We have met with regulatory authorities in several European countries and believe that no additional clinical trials will be required for submission if the ongoing CLIRS trial is successful.

Additional Indications

We intend to pursue a pediatric indication for Omigard for the prevention of catheter-related infections. As in the adult population, CVCs are frequently used in neonates, infants and children with wide variety of conditions. Pediatric CVCs are a significant source of infectious complications in hospitalized children.

We have rights to develop and commercialize omiganan pentahydrochloride for additional indications related to the prevention and treatment of device-related, surgical wound-related and burn-related infections. We believe that omiganan pentahydrochloride may have significant opportunity in these areas. For example, the CDC estimates there are approximately 500,000 post-operative surgical site infections in the United States annually. The CDC also estimates that there are 50,000 hospitalizations from burn injuries and that 10,000 people will die from burn-related infections in the United States every year.

Commercialization Strategy

We intend to build a commercial organization in the United States focused on promoting our products to physicians, nurses and pharmacy directors 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 our products to reach markets outside the United States or to expand our reach to other physician groups outside the hospital where applicable. In particular, we believe that Omigard is an excellent candidate for partnering in countries outside the United States, and we anticipate launching the product in those countries with a partner who has the resources to be competitive in the hospital market.

For the launch of Omigard in the United States, we intend to build our own commercial organization and estimate that a sales force of approximately 75-100 people will reach the top 1,200 institutions, which we believe represents more than 60% of the market opportunity for the product. Sales calls will primarily target anesthesiologists and surgeons. Other targets will include intensive care physicians, infectious disease physicians and infection control physicians and nurses in outpatient dialysis centers, obstetricians and other physicians throughout the hospital. Key elements in the adoption of Omigard will include formulary acceptance followed by trial and usage and, ultimately, adoption to standing orders and protocols within the hospitals and specific units therein. We expect that Omigard will be used as an addition to current care. We intend to initially target Omigard to high risk patients that we believe, based on market research, comprise approximately 47% of patients with CVCs.

For the launch of IV APAP, we intend to expand the sales force to 150-200 people to reach the top 1,800 to 2,000 institutions, which we believe represents more than 80% of the opportunity for both products. The primary target audience will include anesthesiologists and surgeons. Other targets will include certified registered nurse anesthetists, emergency medicine physicians, obstetricians and other physicians throughout the hospital.

Licensing Agreements

IV APAP Agreement

In March 2006, we in-licensed the patents and the exclusive development and commercialization rights to IV APAP in the United States and Canada from BMS. 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 $50.0 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 our affiliates.

The term of the IV APAP 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 IV APAP 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 IV APAP agreement if we breach, in our capacity as a sublicensee, any provision of the agreement between BMS and Pharmatop. The IV APAP agreement will automatically terminate in the event of a termination of the license agreement between BMS and Pharmatop. We may terminate the IV APAP 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 IV APAP 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 Agreement

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 $1.45 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.

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 United States, 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 the on-going Phase III trial for Omigard.

Intellectual Property

IV APAP

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

In February 2006, we entered into a clinical supply agreement with Lawrence Laboratories, an affiliate of BMS, under which Lawrence Laboratories has manufactured clinical supplies of IV APAP and placebo. Under the terms of the agreement, Lawrence Laboratories is obligated to supply us with this single batch of IV APAP and a single batch of placebo at specified prices. With these batches, we believe we will have adequate clinical supplies of our IV APAP product candidate and placebo. The term of the clinical supply agreement generally extends until the earlier of the receipt by us of regulatory approval for IV APAP or December 31, 2008. In addition, the clinical supply agreement terminates upon mutual written consent of the parties, the termination of the IV APAP agreement or our dissolution. Either party may also terminate the clinical supply agreement upon written notice of an uncured, material breach by the other party. For commercial supply, the active pharmaceutical ingredient, or API, acetaminophen is readily available from multiple suppliers. We are currently negotiating with suppliers for commercial supply of the finished drug product for IV APAP.

We have purchased clinical supplies of the API omiganan pentahydrochloride from UCB Bioproducts, which was recently acquired by Lonza Group, Ltd. We have purchased clinical supplies of the Omigard finished drug product from Cardinal Health, Inc. Lonza and Cardinal have produced the clinical supplies which we are using in our Phase III Omigard program. We are currently negotiating with suppliers for commercial supply of the API and finished drug product for Omigard.

Competition

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

IV APAP

Our IV APAP product candidate is being developed for the treatment of acute pain, usually in the hospital setting. A wide variety of competitive products already address this target market, 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 (formerly Corgentech Inc.), CeNeS Pharmaceuticals plc, Cumberland Pharmaceuticals Inc., Durect Corporation, Javelin Pharmaceuticals, Inc., Pfizer Inc., SkyePharma Inc., St. Charles Pharmaceuticals, TheraQuest Biosciences, LLC and Xsira Pharmaceuticals, Inc.

Omigard

We are developing our Omigard product candidate for the prevention of intravascular catheter-related infections. Although there are no approved drugs for this specific indication, a number of topical products are currently used in practice and one device has been approved for wound dressing and prevention of catheter-related infections. These competitive products include:

- topical antiseptics such as povidone-iodine and chlorhexidine, each of which is available generically from several manufacturers;
- Neosporin, a topical antibacterial ointment containing polymyxin, neomycin and bacitracin, available generically from several manufacturers;
- Bactroban, a topical antibacterial containing mupirocin, available generically from several manufacturers; and
- BioPatch, a chlorhexidine-impregnated foam dressing, from Johnson & Johnson that is approved both for wound dressing and the prevention of catheter-related infections.

Other products may be in development; however, we are not aware of any other topical drugs being developed for the prevention of intravascular catheter-related infections.

Government Regulation

Governmental authorities in the United States 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 United States, 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 United States 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 NDAs approved during calendar year 2004 was approximately 13 months for standard applications. 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.

Special Protocol Assessment Process

The special protocol assessment, or SPA, process provides for official FDA evaluation of a proposed Phase III clinical trial protocol and generally provides a product sponsor with a binding agreement from the FDA that the

design and analysis of the trial are adequate to support a license application submission if the trial is performed according to the SPA. The FDA's guidance on the SPA process indicates that SPAs are designed to evaluate individual clinical trial protocols primarily in response to specific questions posed by the sponsors. In practice, the sponsor of a product candidate may request an SPA for proposed Phase III trial objectives, designs, clinical endpoints and analyses. A request for an SPA is submitted in the form of a separate amendment to an IND, and the FDA's evaluation generally will be completed within a 45-day review period under applicable PDUFA goals, provided that the trials have been the subject of discussion at an end-of-Phase II and pre-Phase III meeting with the FDA, or in other limited cases. All agreements and disagreements between the FDA and the sponsor regarding an SPA, including the FDA's responses to questions about protocol design, primary efficacy endpoints, study conduct, data analysis and prospective labeling statements must be documented in writing. In limited circumstances, the FDA may agree that a specific finding, such as a particular p-value on the primary efficacy endpoint of a study, will satisfy a specific objective, such as demonstration of efficacy, or support an approval decision. However, final determinations by the FDA are made after a complete review of the applicable NDA and are based on the entire data in the application, and any SPA is subject to future public health concerns unrecognized at the time of protocol assessment.

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, 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 United States, 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 United States 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 United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

Employees

As of February 28, 2007, we had 35 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.

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 largely dependent on the success of our only two product candidates, IV APAP and Omigard, and we cannot be certain that our planned clinical development programs will be sufficient to support NDA submissions or that either product candidate will receive regulatory approval or be successfully commercialized;*
- *delays in the commencement, enrollment or completion of clinical testing for either of our product candidates could result in increased costs to us and delay or limit our ability to obtain regulatory approval;*
- *even if our product candidates are approved by regulatory authorities, we expect intense competition in the hospital marketplace for our targeted indications;*
- *the patent rights that we have in-licensed covering IV APAP 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 development programs and commercialization efforts.*

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 two product candidates, IV APAP and Omigard, and we cannot be certain that either of these product candidates will receive regulatory approval or be successfully commercialized.

We currently have no drug products for sale and we cannot guarantee that we will ever have marketable drug products. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a new drug application, or NDA, from the FDA. We have not submitted an NDA or received marketing approval for either of our product candidates. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. We currently have only two product candidates, and our business success currently depends entirely on their successful development and commercialization.

We have not developed either of our product candidates independently. In March 2006, we in-licensed exclusive rights to IV APAP, an intravenous formulation of acetaminophen that is currently marketed in Europe for the treatment of acute pain and fever by Bristol-Myers Squibb Company, or BMS. Based on the preliminary

feedback we received from the FDA in our meeting in August 2006, we intend to conduct six additional clinical trials to provide the FDA with data to support multiple dose efficacy for acute pain, efficacy for fever and safety in adults and children. In July 2004, we in-licensed the rights to our only other product candidate, omiganan pentahydrochloride 1% aqueous gel, or Omigard™, which is currently being evaluated in a single Phase III clinical trial for the prevention of local catheter site infections, or LCSIs, and will require the successful completion of this Phase III clinical trial before we are able to submit an NDA to the FDA for approval. Our clinical development programs for IV APAP and Omigard may not lead to commercial products if we fail to demonstrate that the product candidates are safe and effective in clinical trials and we may therefore fail to obtain necessary approvals from the FDA and similar foreign regulatory agencies, or because we may have inadequate financial or other resources to advance these product candidates through the clinical trial process. Any failure to obtain approval of IV APAP or Omigard would have a material and adverse impact on our business.

If clinical trials of our current or future product candidates do not produce results necessary to support regulatory approval in the United States or elsewhere, we will be unable to commercialize these products.

To receive regulatory approval for the commercial sale of IV APAP, Omigard or any other product candidates that we may in-license or acquire, we must conduct, at our own expense, adequate and well controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. For example, Migenix Inc., or Migenix, the licensor for our Omigard product candidate, together with its former collaborator, Fujisawa Healthcare, Inc., or Fujisawa, completed enrollment in a Phase III trial in February 2003 that demonstrated statistically significant results for the secondary endpoints of the trial: the prevention of LCSIs and catheter colonization, which is the growth of microorganisms on the portion of the catheter below the skin surface. However, the trial did not show statistical significance for the primary endpoint, the prevention of catheter-related bloodstream infections, or CRBSIs.

After the termination of the collaboration between Migenix and Fujisawa in January 2004, we in-licensed the rights to Omigard from Migenix in July 2004 and subsequently reached an agreement under the special protocol assessment, or SPA, process with the FDA concerning the protocol for our own Phase III clinical trial for Omigard. In connection with the SPA for Omigard, the FDA agreed that a single confirmatory Phase III trial will be required for approval of Omigard and that the prevention of LCSIs will be the sole primary efficacy endpoint. However, we cannot be certain that our ongoing Phase III trial for Omigard will demonstrate statistical significance or otherwise demonstrate sufficient efficacy and safety to support the filing of an NDA or ultimately lead to regulatory approval. Furthermore, despite having completed the SPA process, the FDA's agreement with us on the trial protocol remains subject to future advances in the field or future public health concerns unrecognized at the time of the FDA's protocol assessment.

Our failure to adequately demonstrate the efficacy and safety of IV APAP, Omigard or any other product candidates that we may in-license or acquire would prevent receipt of regulatory approval and, ultimately, the commercialization of that product candidate.

Because the results of earlier clinical trials are not necessarily predictive of future results, IV APAP, Omigard or any other product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Success in clinical testing and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of the investigational drug. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase III clinical trials, even after promising results in earlier clinical trials.

In March 2006, we in-licensed the rights to IV APAP from BMS, which is currently marketing IV APAP in Europe and other parts of the world under the brand name Perfalgan. BMS has completed nine clinical trials, mostly in Europe, primarily in support of European regulatory approvals for this product candidate. However, we do not know at this time what regulatory weight, if any, the U.S. and Canadian regulatory agencies will give to these

clinical data in supplementing clinical data generated by us for potential regulatory approval of IV APAP in the United States and Canada. The FDA and foreign regulatory agencies may reject these clinical trial results if they determine that the clinical trials were not conducted in accordance with requisite regulatory standards and procedures. Furthermore, we have not audited or verified the accuracy of the primary clinical data provided by BMS and cannot determine their applicability to our regulatory filings. Even though BMS has obtained marketing approval in Europe and other territories for IV APAP, we must conduct additional adequate and well controlled clinical trials in the United States to demonstrate IV APAP's safety and efficacy in specific indications to gain regulatory approval in the United States. We may not be able to demonstrate the same safety and efficacy for IV APAP in our planned Phase III clinical trial as was demonstrated previously by BMS.

Our other product candidate, Omigard, is a novel antimicrobial peptide and is not yet approved in any jurisdiction. No antimicrobial peptide has been approved by the FDA, including two antimicrobial peptides with mechanisms of action similar to Omigard that were studied in Phase III clinical trials. Although Omigard has been studied in more than 750 patients, all of the patients studied were enrolled in trials conducted or sponsored by Migenix or Fujisawa. Since in-licensing rights to Omigard from Migenix in July 2004, we have initiated a Phase III clinical trial in which we are still seeking to enroll the target patient population. We do not expect to complete enrollment in this Phase III clinical trial until the second half of 2007. Similar to IV APAP, we have obtained electronic databases from the completed Phase III trials sponsored by Migenix and Fujisawa, and are currently analyzing these data. We have not audited or verified the accuracy of the primary clinical data provided by our licensor and its former collaborator and cannot determine their applicability to our regulatory filings. Although the Phase III clinical trial for Omigard conducted by Migenix and Fujisawa demonstrated favorable, statistically significant results for the prevention of LCSIs and catheter colonization, secondary endpoints in their trial, we may not observe similar results in our ongoing Phase III clinical trial. Furthermore, the earlier Phase III clinical trial failed to show statistical significance for the primary endpoint of that trial, the prevention of CRBSIs. While we will measure the prevention of CRBSIs as a secondary endpoint in our ongoing Phase III clinical trial for Omigard, our trial is not designed to demonstrate statistical significance for this secondary endpoint. Although we are targeting a different primary endpoint in our trial, the prevention of LCSIs, it is possible that we will experience similar, unexpected results. Failure to satisfy a primary endpoint in a Phase III clinical trial would generally mean that a product candidate would not receive regulatory approval without a further successful Phase III clinical trial.

The data collected from our clinical trials may not be adequate to support regulatory approval of IV APAP, Omigard or any other product candidates that we may in-license or acquire. Moreover, all clinical data reported is taken from databases that may not have been fully reconciled against medical records kept at the clinical sites. Despite the results reported by others in earlier clinical trials for our product candidates, we do not know whether any Phase III or other clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

Delays in the commencement or completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials for IV APAP will be completed on schedule, if at all. Additionally, the still-to-be-initiated clinical trials for IV APAP may not begin on time. Similarly, we may not complete enrollment for our ongoing Phase III clinical trial for Omigard on schedule, or at all. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may not be eligible to participate in or may be required to withdraw from a clinical trial as a result of changing standards of care. The commencement and completion of clinical trials can be delayed for a variety of other reasons, including delays related to:

- reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining regulatory approval to commence a clinical trial;

- obtaining institutional review board approval to conduct a clinical trial at a prospective site;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the same indication as our product candidates; and
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, side effects from the therapy or who are lost to further follow-up.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- new information suggesting unacceptable risk to subjects, or unforeseen safety issues or any determination that a trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may have been introduced to the market and established a competitive advantage.

We expect intense competition in the territories in which we have rights to our product candidates, 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 our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render our product candidates 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 our product candidates obsolete or noncompetitive.

We intend to develop IV APAP for the treatment of acute pain in the hospital setting, which will compete with well established injectable drugs for this and similar indications, including opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, as well as an extended release injectable (epidural) formulation of morphine, DepoDur. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically from several manufacturers and used to treat acute pain. During the time that it will take us to obtain regulatory approval for IV APAP, 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.

We are also developing our Omigard product candidate for the prevention of intravascular catheter-related infections in the hospital setting. If approved, Omigard will compete with well established topical products that are currently used in practice to prevent these infections as well as BioPatch, a device marketed by Johnson & Johnson,

which has been approved for wound dressing and prevention of catheter-related infections. Other competitive products may be under development.

In addition, competitors may seek to develop alternative formulations of our product candidates 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. Furthermore, there are third-party patents covering analogs of omiganan and Migenix has patented analogs of omiganan that are not licensed to us. The commercial opportunity for our product candidates 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 our product candidates. Our competitors may also develop drugs that are more effective, useful and less costly than ours and may also be more successful than us in manufacturing and marketing their products. We also expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize our product candidates in markets outside the United States.

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial success of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by the medical community and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products 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 IV APAP that may be more restrictive than oral formulations of acetaminophen;
- changes in the standard of care for the targeted indications for either of our product candidates could reduce the marketing impact of any superiority claims that we could make following FDA approval;
- limitations inherent in the approved indication for either of our product candidates compared to more commonly-understood or addressed conditions, including, in the case of Omigard, the ability to promote Omigard to hospitals and physicians who may be more focused on an indication specifically for the prevention of CRBSIs compared to the prevention of LCSIs, the primary endpoint in our ongoing Phase III clinical trial; and
- potential advantages over, and availability of, alternative treatments, including, in the case of IV APAP, a number of products already used to treat acute pain in the hospital setting, and in the case of Omigard, a number of competitive topical products as well as a device that has been approved for wound dressing and prevention of catheter-related infections.

Our ability to effectively promote and sell our product candidates 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.

The decreasing use of the comparator product in our clinical trial for Omigard may limit our ability to complete the trial in a timely manner and hinder the competitive profile of this product candidate.

Over the last several years, many hospitals, particularly in the United States, have increased the use of a particular antiseptic, chlorhexidine, as their standard of care to sterilize catheter insertion sites. Although we believe 10% povidone-iodine continues to be used by a sufficient number of hospitals to support continued enrollment of patients in our Phase III clinical trial for Omigard, this changing standard of care limits the number of potential clinical trial sites available to us. Accordingly, it may be difficult for us to maintain the clinical trial sites that we have already retained for the Omigard trial if any of these institutions elects to replace our comparator product with chlorhexidine, and it may take us longer than anticipated to identify and reach terms with additional hospitals to serve as clinical trial sites for the trial. Delays in the completion of enrollment or clinical testing for our ongoing Phase III clinical trial for Omigard and any other studies we may conduct to compare Omigard to chlorhexidine or another topical antiseptic could significantly affect our product development costs, our prospects for regulatory approval and our ability to compete. Furthermore, the decreasing use of 10% povidone-iodine in favor of chlorhexidine could reduce the marketing impact of any superiority claims that we could make following FDA approval. For example, hospitals and physicians may be reluctant to adopt the use of Omigard in combination with chlorhexadine antisepsis for the prevention of local catheter site infections. Even if Omigard is approved by the FDA, if this product candidate does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may be unable to generate sufficient revenues to recover our development costs or otherwise sustain and grow our business.

Even if our product candidates receive regulatory approval, they 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. Any of these restrictions or requirements could adversely affect our potential product revenues. For example, the label ultimately approved for IV APAP, Omigard or any other product candidates that we may in-license or acquire, if any, may include a restriction on the term of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. 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, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates 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 our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.

Our rights to IV APAP are limited to the United States and Canada, and our rights to Omigard are limited to North America and Europe. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding 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 United States 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 United States. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates 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.

We have never marketed a drug before, and if we are unable to establish an effective sales and marketing infrastructure, we will not be able to successfully commercialize our product candidates.

In the United States, we plan to build our own sales force to market our products directly to physicians, nurses, hospitals, group purchasing organizations and third-party payors. We currently do not have significant internal sales, distribution and marketing capabilities. In order to commercialize any of our product candidates, we must either acquire or internally develop sales and marketing capabilities, or enter into collaborations with partners to perform these services for us. The acquisition or development of a hospital-focused sales and marketing infrastructure for our domestic operations will require substantial resources, will be expensive and time consuming and could negatively impact our commercialization efforts, including delay any product launch. 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 our sales and marketing capability or any other capabilities necessary to commercialize any products we may develop, we will need to contract with third parties to market and sell our products. If we are unable to establish adequate sales and marketing capabilities, whether independently or with third parties, we may not be able to generate any product revenue, may generate increased expenses and may never become profitable.

Our product candidates may have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. For example, the adverse events related to IV APAP observed in clinical trials completed to date include transient liver enzyme evaluations, nausea or vomiting and pain or local skin reactions at the injection site. When used outside the current guidelines for administration, acetaminophen has the potential to cause liver toxicity. While administration of acetaminophen in intravenous form is not expected to 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 that the FDA will not

require additional trials or impose more severe labeling restrictions due to liver toxicity or other concerns. Drug-related adverse events observed in clinical trials completed to date for Omigard have been limited to local skin reactions, including redness, swelling, bleeding, itching, bruising and pain. In addition, while these drug-related adverse events have all been related to the skin, including the catheter insertion site, we cannot be certain that other drug-related side effects will not be reported in clinical trials or thereafter.

If either of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product:

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

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

If the government or third-party payors fail to provide coverage and adequate coverage and payment rates for our future products, 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, IV APAP, Omigard or any other product candidates that we may in-license or acquire, if approved, will face competition from other therapies and drugs for these limited hospital financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Governments continue to propose and pass legislation designed to reduce the cost of healthcare. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental controls. 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. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals might change before our product candidates are approved for marketing. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

If we breach any of the agreements under which we license rights to our product candidates from others, we could lose the ability to continue the development and commercialization of our product candidates.

In March 2006, we entered into an exclusive license agreement with BMS relating to our IV APAP product candidate for the United States and Canada, and in July 2004, we entered into an exclusive license agreement with Migenix relating to our Omigard product candidate for North America and Europe. Because we have in-licensed the rights to our two product candidates from third parties, if there is any dispute between us and our licensors regarding our rights under these license agreements, our ability to develop and commercialize these product candidates may be adversely affected. Any uncured, material breach under these license agreements could result in our loss of exclusive rights to the related product candidate and may lead to a complete termination of our product development efforts for the related product candidate.

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

Our license for IV APAP 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 IV APAP. 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 IV APAP product candidate and may lead to a complete termination of our product development and any commercialization efforts for IV APAP.

We rely on third parties to conduct our clinical trials, including our ongoing Phase III clinical program for IV APAP and our ongoing Phase III clinical trial for Omigard. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates on our anticipated timeline or at all.

We intend to rely primarily on third-party CROs to oversee our clinical trials for our IV APAP and Omigard product candidates, and we depend on independent clinical investigators, medical institutions and contract laboratories to conduct our clinical trials. Although we rely on CROs to oversee our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on CROs does not relieve us of these responsibilities and requirements. CROs and investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If our CROs or independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, it will delay the approval of our FDA applications and our introductions of new products. The CROs with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our product candidates. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may have competitive products under development or currently marketed. If independent investigators and CROs assist our competitors, it could harm our competitive position. If any of these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for IV APAP, Omigard or future product candidates.

If the manufacturers upon whom we rely fail to produce our product candidates 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 development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues.

We do not manufacture any of our product candidates, and we do not currently plan to develop any capacity to do so. We do not yet have agreements established regarding commercial supply of either of our product candidates and may not be able to establish or maintain commercial manufacturing arrangements on commercially reasonable terms for IV APAP, Omigard or any other product candidates that we may in-license or acquire. Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate may result in a delay in FDA approval of the product candidate or may impair our ability to manufacture commercial quantities, which would adversely affect our business. For example, our manufacturers will need to produce specific batches of our product candidates to demonstrate acceptable stability under various conditions and for commercially viable lengths of time. We and our contract manufacturers will need to demonstrate to the FDA and other regulatory authorities this acceptable stability data for our product candidates, as well as validate methods and manufacturing processes, in order to receive regulatory approval to commercialize IV APAP, Omigard or any other product candidate. Furthermore, if our commercial manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

We currently have what we believe are adequate clinical supplies of our Omigard and IV APAP product candidates. We are currently negotiating with suppliers for the commercial supply of the finished drug product for IV APAP and commercial supply of API and finished drug product for Omigard. We do not have any long-term commitments from our suppliers of clinical trial material or guaranteed prices for our product candidates or placebos. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Our manufacturers may not perform as agreed. If our manufacturers were to encounter any of these difficulties, our ability to provide product candidates to patients in our clinical trials would be jeopardized.

In addition, all manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements 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. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

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 of our two current product candidates, IV APAP and Omigard, from third parties who conducted the initial development of each 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.

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

As of February 28, 2007, we had 35 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 clinical trials, continue our development activities and commercialize our product candidates. 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 our clinical trials effectively, including our planned Phase III clinical program for IV APAP, which will be conducted at numerous clinical trial sites, and our ongoing Phase III clinical trial for Omigard, which is being conducted at numerous clinical sites;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors and other third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

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

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

We may not be able to attract or retain qualified management and 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 Secretary. If we lose one or more of these key employees, our ability to implement our business strategy successfully 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 a product candidate and may have to limit its commercialization.

The use of our product candidates 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 $10 million annual aggregate coverage limit and additional amounts in selected foreign countries where we are conducting clinical trials. 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 candidates 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.

Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, 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 United States, which may include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. 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 IV APAP in Europe and other countries principally under the brand name Perfalgan. Although Perfalgan is not labeled for sale in the United States and we have an exclusive license from BMS and its licensor to develop and sell our product candidate in the United States, it is possible that hospitals and other users may in the future seek to import Perfalgan rather than purchase IV APAP in the United States for cost-savings or other reasons. We would not receive any revenues from the importation and sale of Perfalgan into the United States.

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

Our third-party manufacturers' 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 candidates and other hazardous compounds. We and our manufacturers 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 or ongoing clinical trials for IV APAP or Omigard 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 candidates may be delayed.

Risks Related to Intellectual Property

The patent rights that we have in-licensed covering IV APAP 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 IV APAP is acetaminophen. There are currently no patents covering the acetaminophen molecule itself in the territories licensed to us, which include the United States and Canada. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as IV APAP 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 United States that claim methods of making acetaminophen. If a supplier of the active pharmaceutical ingredient, or API, for our IV APAP 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. In addition, Injectapap, a formulation of acetaminophen for intramuscular injection was approved by the FDA for the reduction of fever in adults in March 1986 but was withdrawn from the market by McNeil Pharmaceutical in July 1986. Although we are not aware of any announcement regarding the reasons for Injectapap's withdrawal, we believe it was likely withdrawn from the market due to product-related concerns either related to the intramuscular injection mode of administration or the sodium bisulfite in the formulation.

The number of patents and patent applications covering products in the same field as IV APAP 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 our IV APAP product candidate could be significantly harmed if competitors are able to develop an alternative formulation of acetaminophen outside the scope of our in-licensed patents.

The patent rights that we have in-licensed covering Omigard are limited in scope and limited to specific territories.

We have an exclusive license from Migenix for Omigard in North America and Europe for the licensed field, although currently there are issued patents only in the United States and certain European countries. Canadian applications are pending; however, the claims that ultimately issue in Canada may be narrower than the protection obtained in the United States and Europe or may simply not issue at all. In addition, no patent protection has been sought in Mexico. Accordingly, the manufacture, sale and use of Omigard in Mexico by a competitor cannot be prevented. Furthermore, there are third-party patents covering analogs of omiganan and Migenix has patented analogs of omiganan that are not licensed to us. It is possible that competitors having rights to these patents may develop competing products having the same, similar or better efficacy compared to Omigard.

Furthermore, our license agreement with Migenix may be construed to cover only the use of Omigard and other formulations of omiganan for the licensed field, which is the treatment of burn-related, surgical wound-related, or device-related infections. Thus, Migenix or third-party licensees of Migenix may be able to market Omigard for other uses, including treatment of non-surgery related wound infections. We may be unable to prevent physicians from using any such competitive Omigard product off-label for the field licensed to us.

We depend on our licensors for the maintenance and enforcement of our intellectual property and have limited control, if any, over the amount or timing of resources that our licensors devote on our behalf.

We depend on our licensors, BMS and Migenix, to protect the proprietary rights covering IV APAP and Omigard. Regarding IV APAP, either BMS or its licensor, SCR Pharmatop, depending on the patent or application, is responsible for maintaining issued patents and prosecuting patent applications. Regarding Omigard, Migenix is responsible for maintaining issued patents and prosecuting patent applications. We have limited, if any, control over the amount or timing of resources that our licensors devote on our behalf or the priority they place on maintaining these patent rights and prosecuting these patent applications to our advantage. 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. For patents and applications licensed from Migenix, Migenix is obligated to use commercially reasonable efforts to obtain and maintain patent rights covering Omigard in North America and Europe. If Migenix intends to abandon prosecution or maintenance of any patents or applications, they are obligated to notify us, and at that time, we will be granted an opportunity to maintain and prosecute the patents and applications. In such a case, Migenix is required to transfer all necessary rights and responsibilities to facilitate our maintenance and prosecution of the patents and applications. Similar to BMS, however, we cannot be certain that Migenix will perform its contractual obligations as required or that we will be able to adequately assume the prosecution or maintenance of the Omigard-related patents and applications.

As part of a financing transaction, Migenix has pledged as collateral to its lenders the patents and patent applications covering Omigard. While we believe our license agreement with Migenix would survive any foreclosure on these patents and patent applications, we cannot be sure that the lenders will have adequate expertise or resources to properly perform Migenix's obligations to us under the license agreement, including maintaining and prosecuting the 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. In the case of the IV APAP patents, 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. In certain instances, we may be allowed to pursue the infringement claim ourselves. With respect to Omigard, we have the first right to prosecute a third-party for infringement of the in-licensed Migenix patents provided the infringing activities are in North America or Europe and relate primarily to the licensed field of use. Migenix is obligated to reasonably cooperate with any such suit.

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 United States 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. Finally, Migenix is not obligated to defend or assist in our defense of a third-party infringement suit relating to our Omigard product candidate; however, Migenix has the right to control the defense and settlement that relates to the validity and enforceability of claims in the in-licensed Migenix patents.

For a third-party challenge to the SCR Pharmatop in-licensed patents relating to IV APAP, we will have some ability to participate in either SCR Pharmatop's or BMS's defense thereof. In the case that neither party elects to defend the third-party challenge, then we may have the opportunity to defend it. For a third-party challenge to the in-licensed BMS patents relating to IV APAP, BMS has the sole right to defend such challenge. If it chooses not to, 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 IV APAP, Omigard or any other product candidates that we may in-license or acquire and the methods we use to manufacture them, as well as successfully defending these patents 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 United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States 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 United States 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 some of 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 United States. 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 drug 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 United States 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 IV APAP, Omigard or any other product candidate we may in-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 IV APAP, Omigard or any other product candidates that we may in-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 prevention of infections and cover the use of numerous compounds and formulations in our targeted markets. For instance, there is a patent in force in various European countries, with claims that, if valid, may be broad enough in scope to cover the formulation of our Omigard product candidate. It is possible that we may determine it prudent to seek a license to this European patent in order to avoid potential litigation and other disputes. We cannot be sure that a license would be available to us on commercially reasonable terms, or at all. Similarly, there is a patent application pending in the United States that corresponds to the European patent. Because this patent application has neither published nor issued, it is too early to tell if the claims of this application will present similar issues for Omigard in the United States. There is also a patent application pending in Canada that corresponds to the European patent. Because this patent application has not issued, it is too early to tell if the claims of this application will present similar issues for Omigard in Canada. However, similar to the European patent, if the U.S. or Canadian patent applications issue with a scope that is broad enough to cover our Omigard

product candidate and we are unable to assert successful defenses to any patent claims, we may be unable to commercialize Omigard, or may be required to expend substantial sums to obtain a license to the other party's patent. While we believe there may be multiple grounds to challenge the validity of the European patent, and these grounds may be applicable to the U.S. and Canadian applications should they issue as patents, the outcome of any litigation relating to this European patent and the U.S. and Canadian patent applications, or any other patents or patent applications, is uncertain and participating in such litigation would be expensive, time-consuming and distracting to management. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and Migenix 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 IV APAP or Omigard may infringe. There could also be existing patents of which we are not aware that IV APAP or Omigard 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 is not 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 our two product candidates, IV APAP and Omigard, with the goal of supporting regulatory approval for these product candidates. We have financed our operations almost exclusively through private placements of preferred stock and have incurred losses in each year since our inception in May 2004. Net losses were $7.7 million in 2005 and $52.2 million for the year ended December 31, 2006. The net loss for the year ended December 31, 2006 was principally attributed to our expense related to the $25.0 million licensing fee for IV APAP paid to BMS and clinical trial and regulatory expenses. As of December 31, 2006, we had an accumulated deficit of $62.7 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 as well as clinical product

manufacturing expenses to increase in connection with our ongoing and planned Phase III clinical trials for our product candidates. In addition, if we obtain regulatory approval for IV APAP or Omigard, 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 and increasing 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 ongoing and planned clinical trials for IV APAP and Omigard;
- obtain regulatory approval for either of our two product candidates;
- assuming these regulatory approvals are received, manufacture commercial quantities of our product candidates at acceptable cost levels; and
- successfully market and sell any approved products.

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product. 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 our IV APAP product candidate since March 2006 and our Omigard product candidate since July 2004. Our operations to date have been limited to organizing and staffing our company, in-licensing our two product candidates and initiating product development activities for our two product candidates. 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 conduct adequate and well-controlled clinical trials to provide clinical data to support regulatory approval of marketing applications;
- continue our development activities;
- qualify and outsource the commercial-scale manufacturing of our products under cGMP; and
- commercialize IV APAP, Omigard or any other product candidates that we may in-license or acquire, if any of these product candidates receive regulatory approval.

We believe that our existing cash and cash equivalents, including the net proceeds from our initial public offering completed in the fourth quarter of 2006, will be sufficient to meet our projected operating requirements through the end of 2008. We have based this estimate on assumptions that may prove to be wrong, and we could

spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other product development programs for IV APAP, Omigard and any other product candidates that we may in-license or acquire;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- the cost and timing of completion of an outsourced commercial manufacturing supply 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; and
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish.

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 agreements for IV APAP and Omigard;
- our execution of other collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- our addition or termination of clinical trials or funding support;
- variations in the level of expenses related to our two existing product candidates or future development programs;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates or those of our competitors; and
- if either of our product candidates receives regulatory approval, the level of underlying hospital demand for our product candidates 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 which 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 the 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 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 will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Global Market, have imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these new 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, we expect these rules and regulations to 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 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, commencing in fiscal 2007, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

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 develop or 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. 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. 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. Since our initial public offering in October 2006 through March 19, 2007, the trading prices for our common stock ranged from a high of $15.65 to a low of $9.25.

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 will be able to sell in the public market beginning April 23, 2007. 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.

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 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.

We expect that the price of our common stock will fluctuate substantially.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- the results from our clinical trial programs, including our planned Phase III clinical program for IV APAP and our ongoing Phase III clinical trial for Omigard;
- the results of clinical trial programs for IV APAP and Omigard being performed by others;
- FDA or international regulatory actions, including failure to receive regulatory approval for any of our product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- 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 management's attention and resources, which could hurt our business, operating results and financial condition.

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 March 19, 2007, our executive officers and directors and their affiliates will together control approximately 55% 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 loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation restricts our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of 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 2010. We have no laboratory, research or manufacturing facilities. 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***

On October 4, 2006, our stockholders acted by written consent to approve and adopt a Certificate of Amendment to our Amended and Restated Certificate of Incorporation which was filed prior to the effectiveness of our initial public offering and effected a 1-for-4 reverse stock split of our then-outstanding common stock. Stockholders holding an aggregate of 20,418,893 shares approved the above matter and stockholders holding approximately 1,666,647 shares did not consent with respect to such matter.

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 such time, there was no public market for our common stock. The following table sets forth the high and low closing sales prices for our common stock as reported on The Nasdaq Global Market for the periods indicated.

Year Ended December 31, 2006	High	Low
Fourth quarter (beginning October 25, 2006)	13.25	9.25

As of March 19, 2007, there were approximately 81 holders of record of our common stock.

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 and Oxford Finance Corporation. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-135821) that was declared effective by the Securities and Exchange Commission on October 24, 2006, which registered an aggregate of 6,900,000 shares of our common stock. On October 24, 2006, 6,000,000 shares of common stock were sold on our behalf at an initial public offering price of $9.00 per share, for an aggregate gross offering price of $54.0 million, managed by Merrill Lynch & Co., Deutsche Bank Securities, Pacific Growth Equities, LLC and JMP Securities. On November 13, 2006, in connection with the exercise of the underwriters' over-allotment option, 900,000 additional shares of common stock were sold on our behalf at the initial public offering price of $9.00 per share, for an aggregate gross offering price of $8.1 million. Following the sale of the 6,900,000 shares, the offering terminated.

We paid to the underwriters underwriting discounts totaling approximately $4.3 million in connection with the offering. In addition, we incurred additional expenses of $1.9 million in connection with the offering, which when added to the underwriting discounts paid by us, amounts to total expenses of $6.2 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering costs, were $55.9 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of December 31, 2006, we had used approximately $5.9 million of the net proceeds of this offering to fund clinical trials for IV APAP and Omigard and other research and development activities, to fund capital expenditures, primarily including equipment associated with the manufacturing of IV APAP and to fund working capital and other general corporate purposes. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products. We cannot specify with certainty all of the particular uses for the net proceeds from our initial public offering. The amount and timing of our expenditures will depend on several factors, including the progress of our clinical trials and commercialization efforts as well as the amount of cash used in our operations. Accordingly, our management will have broad discretion in the application of the net proceeds.

Recent Sales of Unregistered Securities

During the year ended December 31, 2006, we issued and sold the following unregistered securities:

1. In February 2006, in connection with a loan and security agreement, we issued two warrants to two lenders to purchase an aggregate of 385,000 shares of Series A-2 preferred stock, at an initial exercise price of $1.00 per share, subject to adjustment. These warrants became exercisable for 96,250 shares of our common stock, at an exercise price of $4.00 per share upon the completion of our initial public offering. One of these warrants was net exercised for 27,754 shares in November 2006. The other warrant is exercisable through February 2016 for 48,125 shares of our common stock.

2. In March 2006, we issued and sold an aggregate of 53,870,000 shares of Series A-3 preferred stock to certain existing and new investors at a per share price of $1.00, for aggregate consideration of $53,870,000. Upon completion of our initial public offering, these shares of Series A-3 preferred stock converted into 13,467,498 shares of our common stock.

3. From January 1, 2006 to October 24, 2006, which is the day before we priced our initial public offering of common stock, we granted stock options to purchase 1,799,302 shares of our common stock at exercise prices ranging from $0.40 to $3.20 per share to our employees, consultants and directors under our 2004 equity incentive award plan. From January 1, 2006 to October 24, 2006, we issued and sold an aggregate of 273,935 shares of our common stock to our employees, consultants and directors at prices ranging from $0.40 to $3.20 per share pursuant to exercises of options granted under our 2004 equity incentive award plan.

The issuance of securities described above in paragraphs (1) and (2) were exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(2) of the Securities Act of 1933, as amended, and

Regulation D promulgated thereunder, as transactions by an issuer not involving any public offering. The purchasers of the securities in these transactions represented that they were accredited investors or qualified institutional buyers and they were acquiring the securities for investment only and not with a view toward the public sale or distribution thereof. Such purchasers received written disclosures that the securities had not been registered under the Securities Act of 1933, as amended, and that any resale must be made pursuant to a registration statement or an available exemption from registration. All purchasers either received adequate financial statement or non-financial statement information about the registrant or had adequate access, through their relationship with the registrant, to financial statement or non-financial statement information about the registrant. The sale of these securities was made without general solicitation or advertising.

The issuance of securities described above in paragraph (3) was exempt from registration under the Securities Act of 1933, as amended, in reliance on Rule 701 of the Securities Act of 1933, as amended, pursuant to compensatory benefit plans approved by the registrant's board of directors.

Issuer Repurchases of Equity Securities

Not applicable.

Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes securities available under our equity compensation plans as of December 31, 2006.

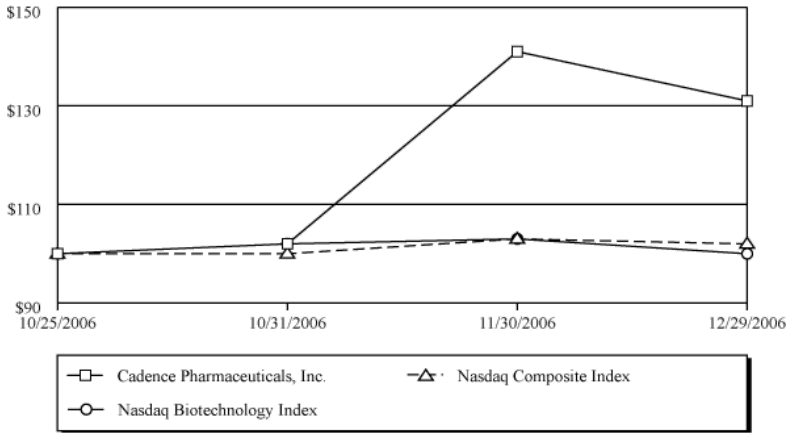
	Shares Issuable Upon Exercise of Outstanding Awards	Weighted Average Exercise Price	Number of Securities Available for Future Issuance
Equity compensation plans approved by security holders:			
2004 Equity Incentive Award Plan	1,651,867	$ 1.97	—
2006 Equity Incentive Award Plan	13,100	$ 11.34	2,177,672
Equity compensation plans not approved by security holders:			
None			

The 2006 Equity Incentive Award Plan was adopted at the time of the initial public offering which coincided with the discontinuance of the 2004 Equity Incentive Award Plan. Stock options under the 2006 Equity Incentive Award Plan have an exercise price equal to the fair market value of the underlying common stock at the date of grant, generally vest over a period of between four years, and have a ten-year life. 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 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. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.

Comparison of Cumulative Total Return on Investment
Since October 25, 2006



	10/25/06	12/29/06
Cadence Pharmaceuticals, Inc.	$100	$131
Nasdaq Composite Index	$100	$102
Nasdaq Biotechnology Index	$100	$100

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. The following selected financial data should be read in conjunction with the Financial Statements and notes thereto and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere herein. Amounts are in thousands, except per share amounts.

	Years Ended December 31,		Period from May 26, 2004 (Inception) through December 31,	Period from May 26, 2004 (Inception) through December 31,
	2006	2005	2004	2006
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 47,827	$ 6,126	$ 1,883	$ 55,836
Marketing	810	240	41	1,091
General and administrative	4,946	1,412	877	7,235
Total operating expenses	53,583	7,778	2,801	64,162
Loss from operations	(53,583)	(7,778)	(2,801)	(64,162)
Other income (expense):				
Interest income	1,945	255	9	2,209
Interest expense	(498)	—	—	(498)
Other expense	(37)	(183)	(45)	(265)
Total other income (expense)	1,410	72	(36)	1,446
Net loss	$ (52,173)	$ (7,706)	$ (2,837)	$ (62,716)
Basic and diluted net loss per share	$ (10.07)	$ (6.67)	$ (3.10)	
Shares used to compute basic and diluted net loss per share	5,182	1,156	915	

	As of December 31,		
	2006	2005	2004
Balance Sheet Data:			
Cash, cash equivalents and securities available-for-sale	$ 86,826	$ 15,025	$ 4,271
Working capital	76,203	14,405	4,161
Total assets	93,322	15,891	4,841
Long-term debt, less current portion	4,662	—	—
Deficit accumulated during the development stage	(62,716)	(10,543)	(2,837)
Total stockholders' equity	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 elsewhere in this 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. Since our inception in 2004, we have in-licensed rights to two product candidates, both of which are currently in Phase III clinical trials. We have in-licensed the exclusive U.S. and Canadian rights to IV APAP, an intravenous formulation of acetaminophen that is currently marketed in Europe for the treatment of acute pain and fever by Bristol-Myers Squibb Company, or BMS. We believe that IV APAP is the only stable, pharmaceutically-acceptable intravenous formulation of acetaminophen. We have also in-licensed the exclusive North American and European rights to omiganan pentahydrochloride 1% aqueous gel, or Omigard ™ , for the prevention and treatment of device-related, surgical wound-related and burn-related infections.

We believe that the hospital setting is a concentrated, underserved market for pharmaceuticals and anticipate building our own, hospital-focused sales force as our product candidates approach 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 United States, or approved in the United States but with significant commercial potential for proprietary new uses or formulations.

We were incorporated in May 2004. During 2004, we focused on hiring our management team and initial operating employees and on in-licensing our first product candidate, Omigard. 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 IV APAP from BMS. In October 2006, we initiated the Phase III clinical development program for IV APAP.

We are a development stage company. We have incurred significant net losses since our inception. As of December 31, 2006, we had an accumulated deficit of $62.7 million. These losses have resulted principally from costs incurred in connection with research and development activities, including license fees, costs of clinical trial activities associated with our current product candidates and general and administrative expenses. We expect to continue to incur operating losses for the next several years as we pursue the clinical development and market launch of our product candidates 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 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 net proceeds of $7.5 million (after underwriting discounts).

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 product candidates ourselves or execute a collaboration arrangement.

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, and costs associated with non-clinical activities, such as regulatory expenses. Our most significant costs are for license fees

and clinical trials. The clinical trial expenses include payments to vendors such as CROs, investigators, clinical suppliers and related consultants. Our historical research and development expenses relate predominantly to the in-licensing of IV APAP and Omigard and clinical trials for Omigard and IV APAP. We charge all research and development expenses to operations as incurred because 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.

We use our internal research and development resources across several projects and many resources are not attributable to specific projects. A substantial portion of our internal costs, including personnel and facility related costs, are not tracked on a project basis and are included in the "other supporting costs" category in the table below.

The following summarizes our research and development expenses for the periods indicated:

Product Candidate	Year Ended December 31, 2006	Year Ended December 31, 2005	Period from May 26, 2004 (Inception) through December 31, 2006
IV APAP	$ 28,052	$ —	$ 28,052
Omigard	14,343	4,802	20,796
Other supporting costs	5,432	1,324	6,988
	$ 47,827	$ 6,126	$ 55,836

At this time, due to the risks inherent in the clinical trial process and given the early stage of our product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for potential commercialization. Clinical development timelines, the probability of success and development costs vary widely. While we are currently focused on advancing each of our product development programs, our future research and development expenses will depend on the determinations we make as to the scientific and clinical success of each product candidate, as well as ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates 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 be substantial over the next few years as we continue the advancement of our product development programs. We initiated our Phase III clinical trial program for Omigard in August 2005. We expect to receive results from the ongoing Omigard clinical trial in the second half of 2007. In the fourth quarter of 2006, we initiated the Phase III clinical development program for IV APAP and expect Phase III clinical trial results to be available in the first half of 2008. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, could cause our research and development expense to increase and, in turn, have a material adverse effect on our results of operations.

Marketing

Our marketing expenses consist primarily of market research studies, salaries, benefits and professional fees related to building our marketing capabilities. We anticipate increases in marketing expenses as we add personnel and continue to develop and prepare for the potential commercialization of our product candidates.

General and Administrative

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 add personnel, comply with the reporting obligations applicable to publicly-held companies, and continue to build our

corporate infrastructure in support of our continued development and preparation for the potential commercialization of our product candidates.

Interest and Other Income

Interest and other income consist primarily of interest earned on our cash, cash equivalents and short-term investments and other-than-temporary declines in the market value of available-for-sale securities.

Income Taxes

As of December 31, 2006, we had both federal and state net operating loss carryforwards of approximately $32.1 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, 2006, we had both federal and state research and development tax credit carryforwards of approximately $1.1 million and $0.3 million, respectively. The federal tax credits will begin expiring in 2024 unless previously utilized and the state tax credits carryforward indefinitely. Under Section 382 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 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 before they expire. 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 recorded any federal or state income tax benefit in our statement of operations.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates.

We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Expenses

A substantial portion of our on-going research and development activities are 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, and no material adjustments to research and development expenses have been recognized. We expect to expand the level of research and development activity performed by external service providers in the future. As a result, we anticipate that our estimated accruals will be more material to our operations in future periods. Subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our results of operations.

Stock-Based Compensation

Effective January 1, 2006, we adopted 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.* SFAS No. 123(R) requires that share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. Prior to SFAS No. 123(R), we disclosed the pro forma effects of applying SFAS No. 123 under the minimum value method. We adopted SFAS No. 123(R) effective January 1, 2006, prospectively for new equity awards issued subsequent to December 31, 2005. The adoption of SFAS No. 123(R) in the first quarter of 2006 resulted in the recognition of $2.1 million of additional stock-based compensation expense for the year ended December 31, 2006.

Under SFAS No. 123(R), we calculate the fair value of stock option grants using the Black-Scholes option-pricing model. The assumptions used in the Black-Scholes model were 5.81-6.08 years for the expected term, 70% for the expected volatility, 4.36-5.08% for the risk free rate and 0% for dividend yield for the year ended December 31, 2006. Future expense amounts for any particular quarterly or annual period could be affected by changes in our assumptions.

The weighted average expected option term for 2006 reflects the application of the simplified method set out in SEC Staff Accounting Bulletin, or SAB, No. 107 which was issued in March 2005. The simplified method defines the life as the average of the contractual term of the options and the weighted average vesting period for all option tranches.

Estimated volatility for fiscal 2006 also reflects the application of SAB No. 107 interpretive guidance and, accordingly, incorporates historical volatility of similar public entities.

As of December 31, 2006, we had approximately $8.4 million of unrecognized share-based compensation costs related to nonvested equity awards.

Prior to January 1, 2006, we applied the intrinsic-value-based method of accounting prescribed by APB Opinion No. 25 and related interpretations. Under this method, if the exercise price of the award equaled or exceeded the fair value of the underlying stock on the measurement date, no compensation expense was recognized. The measurement date was the date on which the final number of shares and exercise price were known and was generally the grant date for awards to employees and directors. If the exercise price of the award was below the fair value of the underlying stock on the measurement date, then compensation cost was recorded, using the intrinsic-value method, and was generally recognized in the statements of operations over the vesting period of the award.

Prior to our initial public offering in October 2006, the fair value of our common stock was established by our board of directors. We have applied the guidance in the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid Series, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, to determine the fair value of our common stock for purposes of setting the exercise prices of stock options granted to employees and others. This guidance emphasizes the importance of the operational development in determining the value of the enterprise. As a development stage enterprise, we were at an early stage of existence, primarily focused on development with an unproven business model. Prior to our initial public offering, we had been funded primarily by venture capitalists with a history of funding start-up, high-risk entities with the potential for high returns in the event the investments are successful.

Prior to the licensing of IV APAP in March 2006, we valued our common stock at the nominal amount of $0.40 per share when we were considered to be in a very early stage of development (stages 1 and 2) as defined in the AICPA guidance, where the preferences of the preferred stockholders, in particular the liquidation preferences, are very meaningful. We utilized an asset-based approach for enterprise value and allocated such value to preferred and common stock based on the current value method. We did not obtain a contemporaneous independent valuation as we were focused on product development and fund raising and believed our board of directors, all of whom are related parties, had the requisite experience at valuing early stage companies.

On June 14, 2006, we commenced the initial public offering process, and based on the preliminary valuation information presented by the underwriters for our initial public offering, we 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, 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, our 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 and we revised the estimate of fair value as discussed below. 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.

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.

Under SFAS No. 123(R), based on the department to which the associated employee reports, we have reported the following amounts of stock-based compensation expense in the statements of operations for the year ended December 31, 2006:

Research and development	$ 561,257
Marketing	1,171
General and administrative	1,572,530
Total stock-based compensation	$ 2,134,958

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. There are also areas in which our management's judgment in selecting any available alternative would not produce a materially different result. Please see our audited financial statements and notes thereto included elsewhere in this Form 10-K, which contain accounting policies and other disclosures required by GAAP.

Results of Operations

Comparison of the years ended December 31, 2006 and 2005

Research and Development Expenses. Research and development expenses increased to $47.8 million for the year ended December 31, 2006 from $6.1 million for the comparable period during 2005. This increase of $41.7 million primarily was due to:

- an increase of $28.1 million in our IV APAP program primarily as a result of a $25.3 million initial license fee which was immediately expensed as in-process research and development;
- an increase of $9.5 million in our Omigard program as a result of clinical trial and related costs for a Phase III clinical trial initiated in August 2005; and
- an increase of $4.1 million in other supporting costs as a result of increased salaries and related personnel costs (including stock-based compensation) from increased research and development staff to support our clinical and regulatory efforts related to both Omigard and IV APAP.

Marketing Expenses. Marketing expenses increased to $0.8 million for the year ended December 31, 2006 from $0.2 million for the comparable period during 2005. This increase of $0.6 million primarily was due to higher market research and branding and personnel costs in 2006.

General and Administrative Expenses. General and administrative expenses increased to $4.9 million for the year ended December 31, 2006 from $1.4 million for the comparable period during 2005. This increase of $3.5 million primarily was due to stock-based compensation charges of $1.6 million and other personnel related charges, our new facility lease and other professional and consulting fees.

Interest Income. Interest income increased to $1.9 million for the year ended December 31, 2006 from $0.3 million for the comparable period during 2005. This increase of $1.6 million primarily was due to the increase in average cash and cash equivalent balances and higher interest rates in 2006.

Interest Expense. Interest expense increased to $0.5 million for the year ended December 31, 2006 from zero for the comparable period during 2005. This increase of $0.5 million was primarily due to interest on the $7.0 million we borrowed from Silicon Valley Bank and Oxford Finance Corporation in June 2006.

Other income (expense). Other income (expense) decreased to approximately $37,000 for the year ended December 31, 2006 from $0.2 million for the comparable period during 2005. The 2006 other income (expense) consists of losses on the disposal of assets related to our facility move and the 2005 amounts consist of impairment charges due to declines in the market value of our Migenix holdings that were determined to be other-than-temporary.

Comparison of year ended December 31, 2005 to the period from May 26, 2004 (inception) through December 31, 2004

Research and Development Expenses. Research and development expenses increased to $6.1 million for the year ended December 31, 2005 from $1.9 million for the period from May 26, 2004 (inception) through December 31, 2004. This increase of $4.2 million primarily was due to:

- an increase of $3.1 million in our Omigard program as a result of clinical trial and related costs offset by a decrease in license fees; and
- an increase of $1.1 million in unallocated expenses as a result of increased salaries and related personnel costs from increased research and development staff to support our initial clinical and regulatory efforts.

Marketing Expenses. Marketing expenses increased to $240,000 for the year ended December 31, 2005 from $41,000 for the period from May 26, 2004 (inception) through December 31, 2004. This increase of $199,000 primarily was due to market research, branding and personnel costs in 2005.

General and Administrative Expenses. General and administrative expenses increased to $1.4 million for the year ended December 31, 2005 from $0.9 million for the period from May 26, 2004 (inception) through December 31, 2004. This increase of $0.5 million primarily was due to salaries and related costs as we expanded our general and administrative functions to support our operations, as well as legal fees, other professional fees and consulting fees.

Interest Income. Interest income increased to $255,000 for the year ended December 31, 2005 from $9,000 for the period from May 26, 2004 (inception) through December 31, 2004. This increase of $246,000 primarily was due to the increase in average cash and investment balances and interest rates in 2005.

Other Expense. Other expense increased to $183,000 for the year ended December 31, 2005 from $45,000 for the period from May 26, 2004 (inception) through December 31, 2004. This increase of $138,000 was due to declines in the market value of our Migenix holdings that were determined to be other-than-temporary.

Liquidity and Capital Resources

Since inception, our operations have been financed primarily through the issuance of our equity securities, in both public and private offerings. Through December 31, 2006, we received net proceeds of approximately $135.6 million from the sale of shares of our preferred and common stock as follows:

- from July 2004 to December 2006 (excluding our initial public offering), we issued and sold a total of 2,285,115 shares of common stock 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 17,675,347 shares of Series A-2 preferred stock for aggregate net proceeds of $17.6 million; and
- 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; and
- 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 an aggregate of $55.9 million.

In February 2006, we entered into a $7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation to provide us with growth capital. We drew down $7.0 million in June 2006 and have no further credit available under this agreement. We are required to make interest only payments on the loan balance for the first six months of the loan, and in February 2007, we began making the first of 30 equal monthly principal and interest payments. Interest accrues on all outstanding amounts at the fixed rate of 11.47%. The loan is collateralized by substantially all of our assets other than intellectual property. We are subject to prepayment penalties. 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.

In conjunction with the loan and security agreement, we issued two warrants to the lenders to purchase 385,000 shares of Series A-2 preferred stock at an exercise price of $1.00 per share. These warrants became exercisable for 96,250 shares of our common stock, at an exercise price of $4.00 per share, upon the completion of our initial public offering. One of these warrants was net exercised for 27,754 shares of our common stock in November 2006.

As of December 31, 2006, we had $86.8 million in cash and cash equivalents. We have invested a substantial portion of our available cash funds in money market funds placed with reputable financial institutions for which credit loss is not anticipated. We have established guidelines relating to diversification and maturities of our securities available-for-sale to preserve principal and maintain liquidity.

Our operating activities used net cash in the amount of $41.7 million and $6.9 million for the year ended December 31, 2006 and 2005, respectively. The increase in net cash used in operating activities from 2005 to 2006 primarily was due to an increase in our net loss as a result of increased development expenses and the $25 million license fee paid for IV APAP. We cannot be certain if, when or to what extent we will receive cash inflows from the commercialization of our product candidates. We expect our development expenses to be substantial and to increase over the next few years as we continue the advancement of our product development programs.

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, IV APAP and Omigard. Pursuant to these agreements, we obtained exclusive licenses to the patent rights and know-how for selected indications and territories. Under the IV APAP agreement, we paid to BMS a $25.0 million up-front fee and may be required to make future milestone payments totaling up to $50.0 million upon the achievement of various milestones related to regulatory or commercial events. Under the Omigard agreement, we paid to Migenix Inc. 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.

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

- the progress of our clinical trials, including expenses to support the trials and milestone payments that may become payable to BMS or Migenix;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements;
- the costs and timing of regulatory approvals;
- the costs involved in enforcing or defending patent claims or other intellectual property rights;
- the costs of establishing sales or distribution capabilities;
- the success of the commercialization of our products; and
- the extent to which we in-license, acquire or invest in other indications, products, technologies and businesses.

We believe that our existing cash and cash equivalents as of December 31, 2006 will be sufficient to meet our projected operating requirements through the end of 2008.

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 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 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. In addition, 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. 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.

Contractual Obligations and Commitments

The following table describes our long-term contractual obligations and commitments as of December 31, 2006:

	Payments Due by Period				
	Total	Less Than One Year	One to Three Years	Four to Five Years	Thereafter
			(In thousands)		
Long-term debt obligations	$ 7,000	$ 2,338	$ 4,662	$ —	$ —
Operating lease obligations	6,401	952	2,187	2,344	918
License obligations(1)	—	—	—	—	—
Total	$ 13,401	$ 3,290	$ 6,849	$ 2,344	$ 918

(1) License obligations do not include additional payments of up to $77.0 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. 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 we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur.

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.

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

Our cash and cash equivalents as of December 31, 2006 consisted primarily of cash and money market 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 invest in may 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 continue to maintain our portfolio of cash equivalents and investment securities available-for-sale in a variety of securities including commercial paper, money market funds and government and non-government debt securities, all with various maturities. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

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, 2006 and 2005, and the related statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2006 and 2005, for the period from May 26, 2004 (inception) through December 31, 2004 and for the period from May 26, 2004 (inception) through December 31, 2006. 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion of the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. 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. (a development stage company), at December 31, 2006 and 2005, and the results of its operations and its cash flows for the year ended December 31, 2006 and 2005, for the period from May 26, 2004 (inception) through December 31, 2004 and for the period from May 24, 2006 (inception) through December 31, 2006 in conformity with generally accepted accounting principles in the United States.

As discussed in Note 1 to the Financial Statements, effective January 1, 2006 Cadence Pharmaceuticals, Inc. changed its method of accounting for share-based payments as required by Statement of Financial Accounting Standards No. 123 (revised 2004).

/s/ Ernst & Young LLP

San Diego, California
March 19, 2007

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

BALANCE SHEETS

	December 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 86,825,526	$ 8,025,285
Securities available-for-sale	—	7,000,000
Prepaid expenses and other current assets	1,168,160	526,173
Total current assets	87,993,686	15,551,458
Property and equipment, net	3,558,618	117,740
Restricted cash	1,233,281	—
Other assets	536,042	222,000
Total assets	$ 93,321,627	$ 15,891,198
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,073,726	$ 715,781
Accrued liabilities	7,378,750	430,220
Current portion of long-term debt	2,338,010	—
Total current liabilities	11,790,486	1,146,001
Deferred rent	1,460,109	—
Long-term debt, less current portion	4,661,990	—
Commitments		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares and 25,760,455 shares issued and outstanding at December 31, 2006 and 2005, respectively	—	2,576
Common stock, $0.0001 par value; 100,000,000 shares authorized; 29,092,720 shares and 1,904,000 shares issued and outstanding at December 31, 2006 and December 31, 2005, respectively	2,909	190
Additional paid-in capital	138,057,890	25,285,280
Accumulated other comprehensive income	64,033	—
Deficit accumulated during the development stage	(62,715,790)	(10,542,849)
Total stockholders' equity	75,409,042	14,745,197
Total liabilities and stockholders' equity	$ 93,321,627	$ 15,891,198

See accompanying notes.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF OPERATIONS

	Years Ended December 31, 2006	Years Ended December 31, 2005	Period from May 26, 2004 (Inception) through December 31, 2004	Period from May 26, 2004 (Inception) through December 31, 2006
Operating expenses:				
Research and development	$ 47,826,761	$ 6,126,226	$ 1,883,357	$ 55,836,344
Marketing	810,315	240,361	41,114	1,091,790
General and administrative	4,946,121	1,411,810	877,146	7,235,077
Total operating expenses	53,583,197	7,778,397	2,801,617	64,163,211
Loss from operations	(53,583,197)	(7,778,397)	(2,801,617)	(64,163,211)
Other income (expense):				
Interest income	1,944,908	255,785	9,380	2,210,073
Interest expense	(497,617)	—	—	(497,617)
Other expense	(37,035)	(183,000)	(45,000)	(265,035)
Total other income (expense)	1,410,256	72,785	(35,620)	1,447,421
Net loss	$ (52,172,941)	$ (7,705,612)	$ (2,837,237)	$ (62,715,790)
Basic and diluted net loss per share	$ (10.07)	$ (6.67)	$ (3.10)	
Shares used to compute basic and diluted net loss per share	5,181,920	1,155,879	914,589	

See accompanying notes.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY
For the Period from May 26, 2004 (inception) through December 31, 2006

	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
	Shares	Amount	Shares	Amount				
Issuance of common stock to founders for cash at $0.004 per share in July	—	$ —	1,125,000	$ 112	$ 4,388	$ —	$ —	$ 4,500
Exercise of common stock options for cash at $0.40 per share in December	—	—	45,000	5	17,995	—	—	18,000
Issuance of Series A-1 preferred stock for cash at $0.94 per share, net of $59,573 of offering costs, in July and August	8,085,108	809	—	—	7,539,620	—	—	7,540,429
Issuance of common stock options for consulting services in November	—	—	—	—	811	—	—	811
Net loss and comprehensive loss	—	—	—	—	—	—	(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
Exercise of common stock options at $0.40 per share in February, June and December, net of the repurchase of 7,500 shares at $0.40 per share	—	—	734,000	73	105,927	—	—	106,000
Issuance of Series A-2 preferred stock for cash at $1.00 per share, net of $57,041 of offering costs, in June and September	17,675,347	1,767	—	—	17,616,539	—	—	17,618,306
Net loss and comprehensive loss	—	—	—	—	—	—	(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
Exercise of common stock options for cash between $0.40 and $3.20 per share	—	—	353,361	36	466,426	—	—	466,462
Cashless warrant exercise	—	—	27,754	3	(3)	—	—	—
Collection of stock subscription receivable	—	—	—	—	187,600	—	—	187,600
Issuance of Series A-3 preferred stock for cash at $1.00 per share, net of $94,987 of offering costs, in March	53,870,000	5,387	—	—	53,769,626	—	—	53,775,013
Issuance of warrants in connection with loan and security agreement in February	—	—	—	—	313,572	—	—	313,572
Automatic conversion of preferred stock in connection with initial public offering	(79,630,455)	(7,963)	19,907,605	1,990	5,973	—	—	—
Initial public offering of common stock at $9.00 per share in October (including over-allotment exercise), net of $6,204,852 of offering costs	—	—	6,900,000	690	55,894,458	—	—	55,895,148
Employee stock-based compensation recognized under SFAS No. 123(R)	—	—	—	—	2,134,958	—	—	2,134,958
Other comprehensive income:								
Unrealized gain on investment securities	—	—	—	—	—	64,033	—	64,033
Net loss	—	—	—	—	—	—	(52,172,941)	(52,172,941)
Total comprehensive loss	—	—	—	—	—	—	—	(52,108,908)
Balance at December 31, 2006	—	$ —	29,092,720	$ 2,909	$ 138,057,890	$ 64,033	$ (62,715,790)	$ 75,409,042

See accompanying notes.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

STATEMENTS OF CASH FLOWS

	Years Ended December 31, 2006	Years Ended December 31, 2005	Period from May 26, 2004 (Inception) through December 31, 2004	Period from May 26, 2004 (Inception) Through December 31, 2006
Operating activities				
Net loss	$ (52,172,941)	$ (7,705,612)	$ (2,837,237)	$ (62,715,790)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	221,681	36,876	8,389	266,946
Loss on disposal of assets	37,034	—	—	37,034
Stock-based compensation	2,134,958	—	811	2,135,769
Non-cash interest expense and impairment charges	91,663	183,000	45,000	319,663
Changes in operating assets and liabilities:				—
Prepaid expenses and other current assets	(322,238)	(470,160)	(56,013)	(848,411)
Accounts payable, accrued liabilities and deferred rent	8,297,581	1,031,527	114,474	9,443,582
Net cash used in operating activities	(41,712,262)	(6,924,369)	(2,724,576)	(51,361,207)
Investing activities				
Purchases of marketable securities	—	(7,000,000)	(450,000)	(7,450,000)
Maturities of marketable securities	7,000,000	—	—	7,000,000
Increase in restricted cash	(1,581,130)	—	—	(1,581,130)
Purchases of property and equipment	(2,509,063)	(45,881)	(117,124)	(2,672,068)
Net cash provided by (used in) investing activities	2,909,807	(7,045,881)	(567,124)	(4,703,198)
Financing activities				
Proceeds from issuance of common stock, net	56,827,683	106,000	22,500	56,956,183
Proceeds from sale of preferred stock, net	53,775,013	17,618,306	7,540,429	78,933,748
Borrowings under debt agreements	7,000,000	—	—	7,000,000
Net cash provided by financing activities	117,602,696	17,724,306	7,562,929	142,889,931
Net increase in cash and cash equivalents	78,800,241	3,754,056	4,271,229	86,825,526
Cash and cash equivalents at beginning of period	8,025,285	4,271,229	—	—
Cash and cash equivalents at end of period	$ 86,825,526	$ 8,025,285	$ 4,271,229	$ 86,825,526
Supplemental schedule of non-cash investing and financing activities:				
Issuance of warrants in connection with loan and security agreement	$ 313,572	$ —	$ —	$ 313,572
Assets acquired through lease concessions	$ 1,190,530	$ —	$ —	$ 1,190,530
Unrealized gain on investment securities	$ 64,033	$ —	$ —	$ 64,033

See accompanying notes.

Cadence Pharmaceuticals, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS

Cadence Pharmaceuticals, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

1. The Company and Summary of Significant Accounting Policies

The Company and Basis of Presentation

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 organizational activities, including recruiting personnel, establishing office facilities, conducting research and development, including clinical trials, and raising capital. To date, the Company has in-licensed rights to two Phase III product candidates. Since the Company has not begun principal operations of commercializing a product candidate, the Company is considered to be in the development stage.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consists of cash and other highly liquid investments with original maturities of three months or less from the date of purchase.

Investment Securities Available-for-Sale

In accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, the Company classifies all securities as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive loss until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. As of December 31, 2005, the carrying value of the investments approximated their fair market value. As of December 31, 2006, the fair value of the Company's sole investment security was in excess of its carrying value.

Fair Value of Financial Instruments

The carrying amount of cash and cash equivalents, accounts payable and accrued liabilities are 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.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and 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.

Property and Equipment

Property and equipment, including leasehold improvements, are stated at cost. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally two to five years. Leasehold improvements are amortized over the shorter of their useful lives or the terms of the related leases.

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. Although the Company has accumulated losses since inception, the Company believes the future cash flows to be received from the long-lived assets will exceed the assets' carrying value and, accordingly, the Company has not recognized any impairment losses through December 31, 2006.

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, or CROs, and costs associated with non-clinical activities, such as regulatory 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, 2006, research and development expenses relate predominantly to the in-licensing and clinical trials of IV APAP and Omigard.

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.

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions of SFAS No. 123(R), *Share-Based Payment*, using the prospective transition method and therefore, prior period results will not be restated.

SFAS No. 123(R)supersedes Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock issued to Employees*, and related interpretations, and revises guidance in SFAS No. 123, *Accounting for Stock-Based Compensation.* Under this transition method, the compensation cost related to all equity instruments granted prior to, but not yet vested as of, the adoption date is recognized based on the grant-date fair value which is estimated in accordance with the original provisions of SFAS No. 123; however, those options issued prior to but unvested on January 1, 2006 and valued using the minimum value method are excluded from the options subject to SFAS No. 123(R). Compensation costs related to all equity instruments granted after January 1, 2006 are recognized at grant-date fair value of the awards in accordance with the provisions of SFAS No. 123(R). Additionally, under the provisions of SFAS No. 123(R), the Company is required to include an estimate of the number of the awards that will be forfeited in calculating compensation costs, which is recognized over the requisite service period of the awards on a straight-line basis.

Under SFAS No. 123(R), based on the department to which the associated employee reports, the Company has reported the following amounts of stock-based compensation expense in the statements of operations for the year ended December 31, 2006:

Research and development	$ 561,257
Marketing	1,171
General and administrative	1,572,530
Total stock-based compensation	$ 2,134,958
Stock-based compensation per share, basic and diluted	$ 0.41

The following table shows the assumptions used to compute the stock-based compensation costs for the stock options granted during the year ended December 31, 2006 using the Black-Scholes option pricing model:

Employee Stock Options	
Risk-free interest rate	4.36 - 5.08%
Dividend yield	0.00%
Expected life of options (years)	5.81 - 6.08
Volatility	70.00%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. 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. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical 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 weighted average grant-date fair value of stock options granted during the year ended December 31, 2006 was $7.03 per share.

As of December 31, 2006, the Company has approximately $8,400,000 of unrecognized stock-based compensation costs related to the non-vested balance of the 1,812,402 stock options granted during the year ended December 31, 2006 (232,102 of which have been early-exercised and remain unvested at December 31, 2006) and expects to recognize such compensation over a weighted average period of 3.18 years.

Prior to January 1, 2006, the Company applied the intrinsic-value-based method of accounting prescribed by APB Opinion No. 25, and related interpretations including Financial Accounting Standards Board ("FASB")

Interpretation No. 44, *Accounting for Certain Transactions involving Stock Compensation — an interpretation of APB Opinion No. 25*, to account for its equity-based awards to employees and directors. Under this method, if the exercise price of the award equaled or exceeded the fair value of the underlying stock on the measurement date, no compensation expense was recognized. The measurement date was the date on which the final number of shares and exercise price were known and was generally the grant date for awards to employees and directors. If the exercise price of the award was below the fair value of the underlying stock on the measurement date, then compensation cost was recorded, using the intrinsic-value method, and was generally recognized in the statements of operations over the vesting period of the award.

The effect on net loss as if the fair-value-based method had been applied to all outstanding and unvested awards in each period would have been less than a $10,000 increase in the net loss for each period in the period from May 26, 2004 (inception) through December 31, 2005. For purposes of disclosures required by SFAS No. 123, the estimated fair value of the options was amortized on a straight-line basis over the vesting period. The fair value of these awards was estimated using the Minimum Value pricing model, with the following weighted-average assumptions for 2004 and 2005: risk-free interest rate of 3.53% and 4.17%, respectively; dividend yield of 0%; expected volatility of 0%; and a life of four years.

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 ("EITF") 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. Compensation expense related to the 2,500 stock options issued to a non-employee was $811 for both the period from May 26, 2004 (inception) through December 31, 2004 and the period from May 26, 2004 (inception) through December 31, 2006. The fair value of these stock options was estimated using the Black-Scholes pricing model, with the following weighted-average assumptions: risk-free interest rate of 4.19%; dividend yield of 0%; expected volatility of 70%; and a life of 10 years.

Comprehensive Loss

The Company has applied SFAS No. 130, *Reporting Comprehensive Income*, which requires that all components of comprehensive income, including net income, be reported in the financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income, 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. The net loss and comprehensive loss were the same for all periods through December 31, 2005. The comprehensive loss was $64,033 less than the net loss for the year ended December 31, 2006 due to unrealized gains on investments.

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.

	Years Ended December 31, 2006	Years Ended December 31, 2005	Period from May 26, 2004 (Inception) through December 31, 2004
Numerator:			
Net loss	$ (52,172,941)	$ (7,705,612)	$ (2,837,237)
Denominator:			
Weighted average common shares outstanding	5,958,035	1,319,367	920,137
Weighted average unvested common shares subject to repurchase	(776,115)	(163,488)	(5,548)
Denominator for basic and diluted earnings per share	5,181,920	1,155,879	914,589
Basic and diluted net loss per share	$ (10.07)	$ (6.67)	$ (3.10)
Outstanding anti-dilutive securities not included in diluted net loss per share calculation			
Preferred stock (as converted)	—	6,440,107	2,021,271
Preferred stock warrants (as converted)	48,125	—	—
Common stock options	1,664,967	289,000	261,250
Common stock subject to repurchase	746,260	691,969	42,188
	2,459,352	7,421,076	2,324,709

2. Securities Available-for-Sale

As of December 31, 2006 and 2005, the Company held $0 and $7,000,000, respectively, of commercial paper issued by U.S. corporations and rated by debt rating agencies.

In addition, as of December 31, 2006 and 2005, the Company held 617,284 shares of Migenix common stock acquired in July 2004 at an initial cost of $450,000. See Note 7 for further discussion of the acquisition of these shares. In 2004 and 2005, the Company recorded non-cash impairment charges on investments of $45,000 and $183,000, respectively, related to decreases in the market value of the Migenix stock.

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. When 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.

3. Property and Equipment

Property and equipment are as follows:

	Useful Lives	December 31, 2006	December 31, 2005
Leasehold improvements	2 years	$ 1,572,690	$ 1,146
Computer equipment and software	3 years	373,502	63,972
Furniture and equipment	5 years	399,480	94,982
Manufacturing equipment	7 years	122,500	—
Construction in-process	—	1,317,852	—
		3,786,024	160,100
Less accumulated depreciation		(227,406)	(42,360)
		$ 3,558,618	$ 117,740

4. Accrued Liabilities

Accrued liabilities are as follows:

	December 31, 2006	December 31, 2005
Clinical trial and related costs	$ 6,067,927	$ 364,030
Wages and related costs	889,391	—
Professional fees	146,005	17,134
Other	275,427	49,056
	$ 7,378,750	$ 430,220

5. Related Party Transactions

From September 2004 through August 2005, the Company paid Cam L. Garner $5,000 per month plus qualified business expenses for his services as chairman of the Company's board of directors under the terms of a consulting agreement between the Company and a limited liability company affiliated with Mr. Garner. The agreement expired on August 31, 2005. From September 2005 to February 2006, the Company continued to pay Mr. Garner $5,000 per month for his services as chairman of the Company's board of directors. In March 2006, Mr. Garner's monthly compensation for his services as chairman of the Company's board of directors was increased to $8,333 per month. For the years ended December 31, 2006 and 2005, the period from May 26, 2004 (inception) through December 31, 2004 and the period from May 26, 2004 (inception) through December 31, 2006, the Company expensed $94,333, $60,000, $20,000 and $174,333, respectively, for payments to Mr. Garner for services as chairman of the Company's board of directors. The unpaid balance as of December 31, 2006, 2005 and 2004 was $0, $10,000 and $20,000, respectively.

During 2004, a stockholder advanced $500,000 for pre-operating expenses and an exclusivity fee due for the collaboration and license agreement with Migenix (see Note 7). The advance was accounted for in accordance with the SEC SAB Topic 5T (SAB No. 79), *Accounting for Expenses or Liabilities Paid by Principal Stockholder(s)*, which requires the Company to record expenses for services paid by stockholders for the benefit of the Company as if such expenses had been paid directly by the Company. The 531,915 shares of Series A-1 preferred stock issued in settlement of the $500,000 advance were valued at $0.94 per share, the price paid by new Series A-1 investors. The transaction was recorded as a $500,000 cash investment in Series A-1 preferred stock by the stockholder and a corresponding cash payment of $500,000 for operating expenses.

6. Commitments

Loan and Security Agreement

In February 2006, the Company entered into a $7,000,000 loan and security 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 loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation and has no further credit available under this agreement. The Company will make interest only payments on growth capital advances until the first day of the month following the six month anniversary of each growth capital advance, at which date the Company will make the first of 30 equal principal and interest payments. Interest accrues on all outstanding amounts at the fixed rate equal to the greater of (a) 10.83% or (b) the Treasury Rate plus 6.25% as of the date the first principal and interest payment is due. The loans are collateralized by substantially all the assets of the Company (excluding intellectual property) and are subject to prepayment penalties. 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. 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.

In connection with the loan and security agreement, the Company issued 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. Excluding certain mergers or acquisitions, the warrants expire in February 2016. The $313,572 fair value of the warrants was determined using the Black-Scholes valuation model, recorded as debt issuance costs which are included as other long-term assets in the accompanying balance sheets, 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%; expected volatility of 70%; and contractual term of 10 years.

Facility Leases

In 2004, the Company subleased its corporate headquarters under a non-cancelable operating lease that expired in September 2006. 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. Monthly rental payments are adjusted on an annual basis and the lease expires in September 2012. As security for the lease, the landlord required a letter of credit in the amount of $1,581,130. The letter of credit is collateralized by a certificate of deposit in the same amount that is classified as restricted cash in the accompanying balance sheet. The required amount subject to the letter of credit and corresponding certificate of deposit will be reduced by 22% on each of the first four anniversaries of the commencement of the lease. Rent expense was $780,646, $190,911, $67,579 and $1,039,136 for the years ended December 31, 2006 and 2005, the period from May 26, 2004 (inception) through December 31, 2004 and the period from May 26, 2004 (inception) through December 31, 2006, respectively. As of December 31, 2006, future minimum payments under the operating lease totals $952,447, $1,074,851, $1,112,206, $1,151,676, $1,191,851 and $917,676 for the years ending December 31, 2007, 2008, 2009, 2010, 2011 and 2012, respectively.

Severance Obligations

In September 2006, Kenneth R. Heilbrunn, M.D., the Company's former Senior Vice President, Clinical Development, resigned. In accordance with the terms of his employment agreement, the Company was obligated to

pay Dr. Heilbrunn a lump-sum cash payment equal to his annual base salary and other benefits for 12 months following his date of termination. The employment agreement also allowed for the acceleration of vesting for those options that would vest one year from the date of termination. The Company recorded a charge for the termination payments and accelerated vesting of options in the aggregate amount of $500,000. As of December 31, 2006, the Company had paid approximately $320,000 and recorded $155,000 of stock-based compensation charges. The remaining balance of $25,000 is expected to be paid during 2007.

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. As consideration for the license, 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. 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. The Company is also obligated to pay a royalty on future net sales (as defined) of the licensed products and has the right to grant sublicenses to affiliates. The Company expects results from Phase III clinical trials for the licensed product in the second half of 2007 but does not expect FDA approval prior to 2008, if at all. Accordingly, all payments related to the Migenix agreement (other than for the acquisition of common stock) have been recorded as research and development expense.

In March 2006, the Company in-licensed the technology and the exclusive development and commercialization rights to its IV APAP product candidate in the United States 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 $50,000,000 upon the achievement of various milestones related to regulatory or commercial events. The Company is also obligated to pay a royalty on net sales of the licensed products and has the right to grant sublicenses to third parties. The Company began Phase III clinical trials for the licensed product in the fourth quarter of 2006 but does not expect FDA approval prior to 2008, if at all. Accordingly, all payments related to the BMS agreement have been recorded 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. The accompanying financial statements and 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.

Stock Options

In connection with the Company’s initial public offering which became effective on October 24, 2006, the 2006 Equity Incentive Award Plan (the “2006 Plan”) became effective. The 2006 Plan initially has 2,100,000 shares

of common stock reserved for issuance. The initial number of reserved shares will be increased by (i) the 90,772 shares of common stock that remained available for issuance under the 2004 Equity Incentive Plan (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. In addition, 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.

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. After one year, the options generally vest 25%. Thereafter, options generally vest monthly in 36 equal 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.

From May 26, 2004 (inception) through October 24, 2006, the fair value of the Company's common stock was established contemporaneously by the Company's board of directors, all of whom are related parties. On June 14, 2006, the Company commenced the initial public offering process, and based on the preliminary valuation information presented by the underwriters, management 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, without the use of an unrelated valuation specialist. Management concluded that the stock options granted to employees and directors in May and June of 2006 were at prices below the reassessed values. The values of the common stock for May and June of 2006 were initially determined by the Company's board of directors. In the reassessment process, 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.

At December 31, 2006 and 2005, respectively, a total of 2,177,672 and 57,000 shares of common stock remained available for issuance under the Company's stock option plans. A summary of the Company's stock option activity and related information are as follows:

	Options Outstanding			
	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options granted	306,250	$ 0.40		
Options exercised	(45,000)	$ 0.40		
Balance at December 31, 2004	261,250	$ 0.40		
Options granted	769,250	$ 0.40		
Options exercised	(741,500)	$ 0.40		
Balance at December 31, 2005	289,000	$ 0.40		
Options granted	1,812,402	$ 2.11		
Options cancelled	(83,074)	$ 0.96		
Options exercised	(353,361)	$ 1.32		
Balance at December 31, 2006	1,664,967	$ 2.04	9.31	$ 17,100,000
Exercisable at December 31, 2006	1,519,731	$ 1.96	9.31	$ 15,700,000

During the period from May 26, 2004 (inception) through December 31, 2004 and the quarterly periods ended March 31, 2005, June 30, 2005, September 30, 2005, December 31, 2005, March 31, 2006, and June 30, 2006 the Company granted options to purchase shares of the Company's common stock in the amount of 306,250, 162,500, 90,000, 47,750, 469,000, 3,750 and 1,383,557, respectively. All such grants had both a fair value for the underlying common stock and exercise price of $0.40 for periods through March 31, 2006. During the quarterly period ended June 30, 2006, the exercise price of 1,124,053 and 259,500 option grants was $1.36 per share and $3.20 per share, respectively, and the fair value for the underlying common stock was $6.60 per share and $7.70 per share, respectively. During the quarterly period ended September 30, 2006, the exercise price of 412,000 option grants was $3.20 per share and the fair value of the underlying common stock was $7.70 per share.

As of December 31, 2006 and 2005, respectively, 94,756 and 85,445 of the outstanding options were vested and 746,260 and 860,062 of the options exercised were subject to repurchase by the Company since they were unvested.

The aggregate grant date fair value of options that vested during the year ended December 31, 2006 was approximately $249,000. The aggregate exercise date intrinsic value of options exercised during the year ended December 31, 2006 was approximately $3,300,000.

Shares Reserved For Future Issuance

The following shares of common stock are reserved for future issuance:

	December 31, 2006
Common stock options granted and outstanding	1,664,967
Common stock issuable upon the exercise of outstanding warrants	48,125
Common stock options reserved for future issuance	2,177,672
	3,890,764

9. Income Taxes

Significant components of the Company's deferred tax assets for federal and state income taxes at December 31, 2006 and 2005 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, 2006	December 31, 2005
Deferred tax assets:		
Net operating loss carryforwards	$ 13,089,000	$ 3,528,000
Tax credit carryforwards	1,405,000	359,000
Capitalized research and development	10,269,000	520,000
Other, net	1,799,000	111,000
Total deferred tax assets	26,562,000	4,518,000
Valuation allowance for deferred tax assets	(26,562,000)	(4,518,000)
Net deferred taxes	$ —	$ —

At December 31, 2006, the Company had federal and state net operating loss carryforwards of approximately $32,124,000 and $32,128,000, respectively. The federal and state tax loss carryforwards will begin to expire in 2024 and 2014, respectively, unless previously utilized. The Company also had federal research and development tax credit carryforwards of approximately $1,148,000 which will begin expiring in 2024 unless previously utilized. The Company had state research and development tax credit carryforwards of approximately $257,000, which carryforward indefinitely.

Utilization of the net operating loss carry forwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

10. Employee Benefit Plan

Effective January 1, 2005, the Company established a 401(k) plan covering substantially all employees. Employees may contribute up to 100% of their compensation per year (subject to a maximum limit prescribed by federal tax law). The Company may elect to make a discretionary contribution or match a discretionary percentage of employee contributions. As of December 31, 2006, the Company had not elected to make any contributions to the plan.

11. Quarterly Financial 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 fiscal 2006 and 2005 are as follows:

	Year Ended December 31, 2006(1)			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Selected quarterly financial data:				
Total operating expenses	$ 29,368,353	$ 6,580,138	$ 7,994,458	$ 9,640,248
Net loss	(29,241,080)	(6,198,805)	(7,782,841)	(8,950,215)
Basic and diluted net loss per common share	$ (23.84)	$ (4.92)	$ (6.01)	$ (0.53)

	Year Ended December 31, 2005(1)			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Selected quarterly financial data:				
Total operating expenses	$ 970,292	$ 2,113,712	$ 2,464,560	$ 2,229,833
Net loss	(999,658)	(2,253,350)	(2,361,709)	(2,090,895)
Basic and diluted net loss per common share	$ (0.88)	$ (1.99)	$ (2.04)	$ (1.74)

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

12. Subsequent Events

Letter of Credit

In connection with the Company's current negotiations with a supplier for commercial supply of the finished drug product for IV APAP, in January 2007 the Company entered into an irrevocable standby letter of credit ("letter of credit") in the amount of $3,268,000. The letter of credit balance is based on anticipated costs to be incurred by the supplier to facilitate the manufacturing of the drug product. The letter of credit is collateralized by a certificate of deposit in the amount of $1,634,000.

Item 9. ***Changes in and Disagreements With Accountants on Accounting and Financial Disclosures***

Not applicable.

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

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

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

Not applicable.

PART III

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

The information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of our Stockholders (the "Proxy Statement"), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2006, and is incorporated in this report by reference.

We have established a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our internet website at www.cadencepharm.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K.

Item 11. ***Executive Compensation***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

PART IV

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

(a) *Documents filed as part of this report.*

(1) *Financial Statements:*

(2) *Financial Statements Schedules:*

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

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

(b) *Exhibits filed as part of this report.*

The following exhibits are filed as part of this report:

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant
3.2(1)	Amended and Restated Bylaws of the Registrant
4.1(1)	Form of the Registrant's Common Stock Certificate
4.2(2)	Amended and Restated Investor Rights Agreement dated February 21, 2006
4.3(2)	Warrant issued by Registrant in February 2006 to Silicon Valley Bank
4.4(2)	Warrant issued by Registrant in February 2006 to Oxford Finance Corporation
10.1#(3)	Form of Director and Executive Officer Indemnification Agreement
10.2#(3)	Form of Executive Officer Employment Agreement
10.3#(4)	2004 Equity Incentive Award Plan and forms of option agreements thereunder
10.4#(3)	Director Compensation Policy
10.5#(4)	2006 Equity Incentive Award Plan and forms of option and restricted stock agreements thereunder
10.6(3)	Form of Amended and Restated Restricted Common Stock Purchase Agreement
10.7#(3)	2006 Corporate Bonus Plan
10.8(2)	Lease dated May 12, 2006 by and between the Registrant and Prentiss/Collins Del Mar Heights LLC
10.9†(5)	Collaboration and License Agreement dated July 30, 2004 by and between the Registrant and Migenix Inc. (formerly Micrologix Biotech Inc.)

Exhibit Number	Description
10.10†(5)	IV APAP Agreement (US and Canada) dated February 21, 2006 by and between the Registrant and Bristol-Myers Squibb Company
10.11†(5)	License Agreement dated December 23, 2002 by and among SCR Pharmatop and Bristol-Myers Squibb Company
10.12†(2)	Loan and Security Agreement dated February 17, 2006 by and among the Registrant, Silicon Valley Bank and Oxford Finance Corporation
10.13†(5)	Clinical Supply Agreement dated February 21, 2006 by and between the Registrant and Lawrence Laboratories
10.14†(5)	Engagement Letter dated May 19, 2005 by and between the Registrant and Clearview Projects, Inc.
10.15†(6)	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.)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14 and Rule 15d-14 of the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14 and Rule 15d-14 of the Securities Exchange Act of 1934, as amended
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

# 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.

* These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of Cadence Pharmaceuticals, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

(1) Filed with the Registrant's Quarterly Report on Form 10-Q on November 30, 2006 for the quarter ended September 30, 2006.

(2) Filed with the Registrant's Registration Statement on Form S-1 on July 17, 2006.

(3) Filed with Amendment No. 1 to the Registrant's Registration Statement on Form S-1 on August 30, 2006.

(4) Filed with the Registrant's Registration Statement on Form S-8 on October 26, 2006.

(5) Filed with Amendment No. 2 to the Registrant's Registration Statement on Form S-1 on September 25, 2006.

(6) Filed with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 on October 10, 2006.

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 and Chief Executive Officer

Dated: March 28, 2007

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

Signature	Title	Date
/s/ Theodore R. Schroeder Theodore R. Schroeder	President, Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2007
/s/ William R. LaRue William R. LaRue	Senior Vice President, Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 28, 2007
/s/ Cam L. Garner Cam L. Garner	Chairman of the Board of Directors	March 28, 2007
/s/ Brian G. Atwood Brian G. Atwood	Director	March 28, 2007
/s/ Samuel L. Barker, Ph.D. Samuel L. Barker, Ph.D.	Director	March 28, 2007
/s/ Michael A. Berman, M.D. Michael A. Berman, M.D.	Director	March 28, 2007
/s/ James C. Blair, Ph.D. James C. Blair, Ph.D.	Director	March 28, 2007
/s/ Alan D. Frazier Alan D. Frazier	Director	March 28, 2007
/s/ Alain B. Schreiber, M.D. Alain B. Schreiber, M.D.	Director	March 28, 2007
/s/ Christopher J. Twomey Christopher J. Twomey	Director	March 28, 2007

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Theodore R. Schroeder, certify that:

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

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

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

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

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

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

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

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

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

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

Date: March 28, 2007

/s/ Theodore R. Schroeder
Theodore R. Schroeder
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William R. LaRue, certify that:

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

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

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

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

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

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

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

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

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

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

Date: March 28, 2007

/s/ William R. LaRue
William R. LaRue
Senior Vice President, Chief Financial Officer, Treasurer and Secretary

Exhibit 32.1

Certifications
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report of Cadence Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on Form 10-K for the period ended December 31, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Theodore R. Schroeder, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 28, 2007

/s/ Theodore R. Schroeder
Theodore R. Schroeder
President and Chief Executive Officer
(principal executive officer of the registrant)

In connection with the Report, I, William R. LaRue, Senior Vice President, Chief Financial Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 28, 2007

/s/ William R. LaRue
William R. LaRue
Senior Vice President, Chief Financial Officer, Treasurer and Secretary
(principal financial and accounting officer of the registrant)

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