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Filed pursuant to Rule 424(b)(4)
Registration No. 333-135821

PROSPECTUS

6,000,000 Shares

Common Stock

This is our initial public offering. We are offering 6,000,000 shares of common stock.

The initial public offering price is $9.00 per share. Currently, no public market exists for our common stock. Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "CADX."

Investing in our common stock involves risks that are described in the "Risk Factors" section beginning on page 8 of this prospectus.

	Per Share	Total
Public offering price	$ 9.00	$ 54,000,000
Underwriting discount	$.63	$3,780,000
Proceeds, before expenses, to us	$ 8.37	$ 50,220,000

The underwriters may also purchase up to an additional 900,000 shares of common stock from us at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus to cover overallotments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares of common stock will be ready for delivery on or about October 30, 2006.

Merrill Lynch & Co.

Deutsche Bank Securities

Pacific Growth Equities, LLC

JMP Securities

The date of this prospectus is October 24, 2006.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with information different from or in addition to that contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary does not contain all of the information you should consider before buying shares of our common stock. You should read the entire prospectus carefully, especially the "Risk Factors" section and our financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in shares of our common stock. Unless the context requires otherwise, references in this prospectus to "Cadence," "we," "us" and "our" refer to Cadence Pharmaceuticals, Inc.

Cadence Pharmaceuticals, Inc.

Our Company

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 Phase III product candidates, both of which have been studied in prior Phase III clinical trials conducted by our licensors. 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.

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 data from IMS Health Inc., or IMS, an independent marketing research firm, 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. In contrast, 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. 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.

Our 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, over 251 million units of injectable analgesics, typically used to treat acute pain, were sold in the United States in 2005. Opioids 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 in the United States for the treatment of acute pain. 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.

Acetaminophen was first available for sale in the United States in 1955 when it was introduced under the brand name Tylenol. Acetaminophen is the most widely used drug for pain relief and the reduction of fever in the United States and is currently available in over 600 pharmaceutical products. Historically, poor stability in aqueous solutions and inadequate solubility of acetaminophen prevented the development of an intravenous dosage form. The patent protection for IV APAP extends through various dates in 2017 to 2021. Our patent protection for IV APAP is limited to a specific intravenous formulation of acetaminophen and extends through various dates in 2017 to 2021. There are currently no patents covering the acetaminophen molecule itself in the territories licensed to us, which include the United States and Canada.

IV APAP has previously been studied in six completed Phase III trials by BMS principally to support a Marketing Authorization Application in Europe for multiple indications, including pain and fever in both adults and children. Since its introduction in Europe in mid-2002, over 100 million doses of IV APAP have been administered to patients, and it has become the market share leader among injectable analgesics, with 2005 sales of more than $140 million according to IMS. In the fourth quarter of 2006, we expect to initiate the remaining Phase III clinical trial requirements for potential approval in the United States. We expect these Phase III clinical trial results to be available in the first half of 2008 and, if positive, to subsequently submit a new drug application, or NDA, for IV APAP in the second half of 2008. However, we cannot be certain that the FDA will not require additional trials or that IV APAP will ever receive regulatory approval in the United States.

Omigard for the Prevention of Intravascular Catheter-Related Infections

We are currently developing Omigard for the prevention of intravascular catheter-related infections. 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: local catheter site infections, or 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 estimates that there are 250,000 CRBSIs among hospitalized patients 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 cleanse the skin surface around the catheter insertion site prior to insertion. However, the utility of these antiseptics is limited, principally due to their 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 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. We have 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 from Migenix Inc. The patent protection for Omigard extends through various dates in 2017 to 2022.

Omigard has previously been studied in a large, completed Phase III trial that demonstrated statistically significant outcomes for the prevention of LCSI and 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. However, despite the favorable, statistically significant results for prevention of LCSI and catheter colonization, the study did not show statistical significance for the primary endpoint, the prevention of CRBSIs. After in-licensing Omigard, we reached agreement with the FDA through the special protocol assessment, or SPA, process on the trial design, endpoints and statistical analysis plan for a single confirmatory Phase III clinical trial with a primary endpoint of prevention of LCSIs. The 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. We initiated this Phase III clinical trial in August 2005 and expect the results to be available in the second half of 2007 and, if positive, to subsequently submit an NDA for Omigard in the first half of 2008.

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. Specifically, we intend to:

- *Obtain regulatory approval for our Phase III hospital product candidates.* 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, we plan to resume a U.S. Phase III program later this year for IV APAP previously initiated by BMS, and we expect to submit an NDA in the second half of 2008 based on the previously completed trials 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, we believe the number of institutions in the hospital marketplace is relatively limited and 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. 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, including new indications, dosage forms or delivery systems.
- *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 Omigard for additional indications related to the prevention and treatment of device-related, surgical wound-related and burn-related infections.

Risk Factors

We are a development stage company with no revenues, and our operations to date have generated substantial and increasing needs for cash. Our net loss was $7.7 million in 2005, and as of June 30, 2006, we had an accumulated deficit of $46.0 million. Our business and our ability to execute on our business strategy are subject to a number of risks that you should be aware of before you decide to buy our common stock. In particular, you should consider the following risks, which are discussed more fully in "Risk Factors" beginning on page 8:

- 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.

Corporate Information

We were incorporated in Delaware on May 26, 2004. Our principal executive offices are located at 12481 High Bluff Drive, Suite 200, San Diego, California 92130, and our telephone number is (858) 436-1400. Prior to November 2004, we were named Strata Pharmaceuticals, Inc. Our website address is http://www.cadencepharm.com. The information on, or accessible through, our website is not part of this prospectus.

The U.S. Patent and Trademark Office has issued a Notice of Allowance in connection with our intent-to-use trademark application for the mark CADENCE™, covering pharmaceutical preparations for the treatment or prevention of diseases or infections of the body's major organs, including the heart, lungs, liver and kidneys; pharmaceutical preparations for the treatment or prevention of diseases of the body's systems, including the immune system and the cardiovascular system; and pharmaceutical preparations to treat or manage pain, anesthesia, surgical and medical procedures. A Notice of Allowance is a notice issued by the U.S. Patent and Trademark Office to an intent-to-use application once all steps of the application process have been completed. Once the Notice of Allowance has been issued, the applicant has six months to file a statement of use or an extension, showing that it is using the mark in commerce, in order for the U.S. Patent and Trademark Office to issue a certificate of registration. We are developing commercial names for our product candidates, and have applied for U.S. trademark registration for Omigard™. This prospectus also contains trademarks of others, including Bactroban®, Betadine®, BioPatch®, DepoDur®, Dermagraft®, Habitrol®, Lotensin®, Neosporin®, Perfalgan®, Pro-Dafalgan®, Toradol® and Tylenol®.

THE OFFERING

Common stock offered	6,000,000 shares
Common stock to be outstanding after this offering	28,045,540 shares
Use of proceeds	We expect to use the net proceeds from this offering to fund clinical trials and other research and development activities, and to fund working capital, capital expenditures 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.
Risk factors	See "Risk Factors" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.
Nasdaq Global Market symbol	CADX

The number of shares of common stock to be outstanding after this offering is based on 22,045,540 shares outstanding as of June 30, 2006, and excludes:

- 1,442,372 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2006 at a weighted average exercise price of $1.52 per share;
- 96,250 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2006 at a weighted average exercise price of $4.00 per share; and
- 2,519,693 shares of common stock reserved for future issuance under our 2006 equity incentive award plan, which will become effective on the day prior to the day on which we become subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act (including 419,693 shares of common stock reserved for future grant or issuance under our 2004 equity incentive award plan, which shares will be added to the shares to be reserved under our 2006 equity incentive award plan upon the effectiveness of the 2006 equity incentive award plan).

Except as otherwise indicated, all information in this prospectus assumes:

- no exercise by the underwriters of their option to purchase up to an additional 900,000 shares of common stock to cover overallotments;
- the filing of our amended and restated certificate of incorporation and amended and restated bylaws upon completion of this offering;
- the conversion of all outstanding shares of our preferred stock into 19,907,605 shares of common stock upon completion of this offering; and
- a one-for-four reverse stock split of our common stock effected in October 2006.

SUMMARY FINANCIAL DATA

The following table summarizes certain of our financial data. The summary financial data are derived from our audited financial statements for the period from May 26, 2004 (inception) through December 31, 2004, and the year ended December 31, 2005. Data are also derived from our unaudited financial statements for the six-month periods ended June 30, 2005 and 2006, and for the period from May 26, 2004 (inception) through June 30, 2006. The data should be read together with our financial statements and related notes, "Selected Financial Data," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus. The pro forma as adjusted balance sheet data gives effect to the conversion of all outstanding shares of our preferred stock into 19,907,605 shares of our common stock and our sale of 6,000,000 shares of our common stock in this offering at the initial offering price of $9.00 per share, after deducting the underwriting discounts and commissions and estimated offering costs payable by us.

	Period from May 26, 2004 (Inception) Through December 31, 2004	Year Ended December 31, 2005	Six Months Ended June 30,		Period from May 26, 2004 (Inception) Through June 30, 2006
			2005	2006	
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Operating expenses:					
Research and development	$ 1,883	$ 6,126	$ 2,402	$ 33,664	$ 41,674
Marketing	41	240	142	317	598
General and administrative	877	1,412	540	1,968	4,257
Total operating expenses	2,801	7,778	3,084	35,949	46,529
Loss from operations	(2,801)	(7,778)	(3,084)	(35,949)	(46,529)
Other income (expense):					
Interest income	9	255	14	553	818
Interest expense	—	—	—	(44)	(44)
Impairment of investment securities	(45)	(183)	(183)	—	(228)
Total other income	(36)	72	(169)	509	546
Net loss	$ (2,837)	$ (7,706)	$ (3,253)	$ (35,440)	$ (45,983)
Basic and diluted net loss per share(1)	$ (3.10)	$ (6.67)	$ (2.87)	$ (28.50)	
Shares used to compute basic and diluted net loss per share(1)	915	1,156	1,132	1,244	
Pro forma basic and diluted net loss per share(1)		$ (1.49)		$ (2.41)	
Shares used to compute pro forma basic and diluted net loss per share(1)		5,162		14,678	

(1) See Note 1 of Notes to Financial Statements for an explanation of the method used to compute the historical and pro forma net loss per share and the number of shares used in the computation of the per share amounts.

	As of June 30, 2006	
	Actual	Pro Forma As Adjusted
	(In thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 42,881	$ 91,341
Working capital	37,476	85,936
Total assets	46,477	94,937
Long-term debt, less current portion	5,968	5,968
Deficit accumulated during the development stage	(45,983)	(45,983)
Total stockholders' equity	34,550	83,010

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this prospectus, before deciding whether to invest in shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations or growth prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

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. We recently 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. We intend to conduct six clinical trials to provide the FDA with data to support multiple dose efficacy for soft tissue surgery, efficacy for fever and safety in adults and children, based on the preliminary feedback we received from the FDA in our meeting in August 2006. 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 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 begin on time or be completed on schedule, if at all. 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;
- 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 formulation of morphine, DepoDur, currently marketed by an affiliate of Endo Pharmaceuticals Holdings Inc. 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.

The SPA that we agreed to with the FDA for our ongoing Phase III clinical trial for Omigard requires that Omigard be compared to 10% povidone-iodine, a topical antiseptic used to sterilize catheter insertion sites. Although the SPA generally provides us with a binding agreement from the FDA that, assuming positive results, the design and analysis of our ongoing Omigard trial are adequate to support an NDA filing, all SPAs are subject to future public health concerns unrecognized at the time of protocol assessment.

After we established the SPA and commenced our clinical trial, many hospitals, particularly in the United States, began increasing use of another topical antiseptic, chlorhexidine, as the 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 as a single agent 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 planned 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 conduct 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 product candidate. We entered into a clinical supply agreement with Lawrence Laboratories, an affiliate of BMS, under which Lawrence Laboratories has manufactured a single batch of clinical supplies of IV APAP and a single batch of placebo. 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 could terminate upon mutual written consent of the parties, the termination of the IV APAP agreement or our dissolution. The clinical supply agreement may also be terminated by either party upon written notice to the other party of an uncured, material breach. We are currently negotiating with suppliers for the potential commercial supply of the finished drug product for IV APAP. 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 June 30, 2006, we had 24 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. To support this growth, we expect to hire approximately 20 additional employees within the next 12 months at an estimated cost of $2.5 million. We are not in a position to provide a meaningful estimate of our staffing needs beyond the next 12 months. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Furthermore, our staffing estimates are based on

assumptions that may prove to be wrong. 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 $2.8 million in 2004, $7.7 million in 2005 and $35.4 million for the first six months of 2006. The net loss for the first six months of 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 June 30, 2006, we had an accumulated deficit of $46.0 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 will be sufficient to meet our projected operating requirements through at least June 30, 2007. 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 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 operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly 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 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 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 will need to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will 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 2008, 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.

Prior to this offering, there has been no public market for our common stock, and there can be no assurance that a regular trading market will develop and continue after this offering or that the market price of our common stock will not decline below the initial public offering price. The initial public offering price was determined through negotiations between us and the representatives of the underwriters and may not be indicative of the market price of our common stock following this offering. Among the factors considered in such negotiations were prevailing market conditions, certain of our financial information, market valuations of other companies that we and the representatives of the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant. See "Underwriting" for additional information.

As a new investor, you will experience immediate and substantial dilution in the net tangible book value of your shares.

The initial public offering price of our common stock in this offering is considerably more than the net tangible book value per share of our outstanding common stock. Investors purchasing shares of common stock in this offering will pay a price that substantially exceeds the value of our tangible assets after subtracting liabilities. As a result, investors will:

- incur immediate dilution of $6.04 per share, based on the initial public offering price of $9.00 per share; and
- contribute 40% of the total amount invested to date to fund our company based on the initial offering price to the public of $9.00 per share, but will own only 21% of the shares of common stock outstanding after the offering.

To the extent outstanding stock options or warrants are exercised, there will be further dilution to new investors.

We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our projected operating requirements through at least June 30, 2007. However, because we will need to raise additional capital to fund our clinical development programs, among other things, we may conduct substantial additional equity offerings. These future equity issuances, together with the exercise of outstanding options or warrants and any additional shares issued in connection with acquisitions, will result in further dilution to investors.

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

The initial public offering price for the shares of our common stock sold in this offering has been determined by negotiation between the representatives of the underwriters and us. This price may not reflect the market price of our common stock following this offering. The price of our common stock may decline. In addition, 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 management team may invest or spend the proceeds of this offering in ways in which you may not agree or in ways which may not yield a return.

Our management will have broad discretion over the use of proceeds from this offering. The net proceeds from this offering will be used to fund clinical trials and other research and development activities, and to fund working capital, capital expenditures 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 have no present understandings, commitments or agreements with respect to any such in-licenses, acquisitions or investments and no portion of the net proceeds has been allocated for any specific transaction. Our management will have considerable discretion in the application of the net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not increase our operating results or market value. Until the net proceeds are used, they may be placed in investments that do not produce significant income or that lose value.

Future sales of our common stock may depress our stock price.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have 28,045,540 outstanding shares of common stock based on the number of shares outstanding as of June 30, 2006. This includes the shares that we are selling in this offering, which may be resold in the public market immediately. Of the remaining shares, 22,045,540 shares are currently restricted as a result of securities laws or lock-up agreements but will be available for resale in the public market as described in the "Shares Eligible for Future Sale" section of this prospectus. As a result of the lock-up agreements between our underwriters and our security holders and the provisions of Rule 144, Rule 144(k) and Rule 701 under the Securities Act, the shares of our common stock (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

- 4,159,206 shares will be eligible for sale under Rule 144(k) or Rule 701 upon the expiration of the lock-up agreements, beginning 180 days after the date of this prospectus;
- 17,886,334 shares will be eligible for sale under Rule 144 upon the expiration of the lock-up agreements, subject to volume limitations, manner of sale requirements and other restrictions, beginning 180 days after the date of this prospectus;

- 441,480 shares will be eligible for sale, upon exercise of vested options, upon the expiration of the lock-up agreements, beginning 180 days after the date of this prospectus; and
- 96,250 shares will be eligible for sale, upon exercise of outstanding warrants, upon the expiration of the lock-up agreements, beginning 180 days after the date of this prospectus.

Moreover, after this offering, holders of approximately 21,330,113 shares of common stock and the holders of warrants to purchase 96,250 shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. These rights will continue following this offering and will terminate seven years following the completion of this offering, or for any particular holder with registration rights, at such time following this offering when all securities held by that stockholder subject to registration rights may be sold pursuant to Rule 144 under the Securities Act. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements described in the "Underwriting" section of this prospectus.

Our executive officers and directors and their affiliates will exercise control over stockholder voting matters in a manner that may not be in the best interests of all of our stockholders.

Immediately following this offering, our executive officers and directors and their affiliates will together control approximately 56.8% 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, which are to become effective at the closing of this offering, 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements, including statements regarding the progress and timing of clinical trials, the safety and efficacy of our product candidates, the goals of our development activities, estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities to support our products, projected cash needs and our expected future revenues, operations and expenditures. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These risks and uncertainties include, among others:

- our ability to successfully complete clinical development of our only two product candidates, IV APAP and Omigard, on expected timetables, or at all, which includes enrolling sufficient patients in our clinical trials and demonstrating the safety and efficacy of these product candidates in such trials;
- the content and timing of submissions to and decisions made by the FDA and other regulatory agencies, including foreign regulatory agencies, demonstrating to the satisfaction of the FDA and such other agencies the safety and efficacy of our product candidates;
- intense competition in our markets and the ability of our competitors, many of whom have greater resources than we do, to offer different or better therapeutic alternatives than our product candidates;
- market acceptance of and future development and regulatory difficulties relating to any product candidates for which we do receive regulatory approval;
- our ability to develop sales, distribution and marketing capabilities or enter into agreements with third parties to sell, distribute and market any of our product candidates that may be approved for sale;
- our ability to obtain coverage and reimbursement for any of our product candidates that may be approved for sale from the government or third-party payors, and the extent of such coverage and reimbursement, and the willingness of hospitals to pay for our product candidates versus less expensive therapies;
- our compliance with the agreements under which we license the rights to our product candidates;
- our reliance on third parties to conduct our clinical trials and manufacture our product candidates;
- our ability to grow our business by identifying and acquiring or in-licensing new product candidates, increasing the size of our organization and attracting and retaining key personnel;
- our and our licensors’ ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of our product candidates and the rights relating thereto; and
- our short operating history, our lack of revenue and profitability, our significant historical operating losses and our ability to obtain additional funding to continue to operate our business, which funding may not be available on commercially reasonable terms, or at all.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “predict,” “potential,” or the negative of those terms, and similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. These forward-looking statements represent our estimates and assumptions only as of the date of this prospectus and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $48.5 million from the sale of the shares of common stock offered in this offering, based on the initial public offering price of $9.00 per share and after deducting the underwriting discounts and commissions and estimated offering costs payable by us.

The principal purposes for this offering are to fund clinical trials and other research and development activities, including with respect to our two product candidates, to fund our working capital, to make capital expenditures, for other general corporate purposes, to create a public market for our common stock, to increase our ability to access the capital markets in the future and to provide liquidity for our existing stockholders.

We currently expect to use our net proceeds from this offering as follows:

- approximately $43.1 million to fund clinical trials for IV APAP and Omigard and other research and development activities;
- approximately $3.0 million to fund capital expenditures, primarily including equipment associated with the manufacturing of IV APAP; and
- the remainder to fund working capital and other general corporate purposes.

We anticipate that the net proceeds from this offering, together with our existing cash and cash equivalents, will allow us to complete the clinical trials necessary to support NDA filings for IV APAP and Omigard.

We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products. However, we have no current understandings, commitments or agreements to do so.

The amounts and timing of our actual expenditures will depend on numerous factors, including the progress in, and costs of, our clinical trials and other product development programs. We therefore cannot estimate the amount of net proceeds to be used for all of the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

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.

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2006:

- on an actual basis; and
- on a pro forma as adjusted basis to reflect the conversion of all outstanding shares of our preferred stock into 19,907,605 shares of common stock and our receipt of the net proceeds from this offering, based on the initial public offering price of $9.00 per share and after deducting the underwriting discounts and commissions and estimated offering costs payable by us.

The pro forma information below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes appearing elsewhere in this prospectus.

	As of June 30, 2006	
	Actual	Pro Forma as Adjusted
	(In thousands, except share and par value amounts)	
Cash and cash equivalents	$ 42,881	$ 91,341
Long-term debt, less current portion	$ 5,968	$ 5,968
Stockholders' equity:		
Preferred stock, $0.0001 par value actual and pro forma as adjusted; actual — 80,015,455 shares authorized; 79,630,455 issued and outstanding; pro forma as adjusted — 10,000,000 shares authorized; no shares issued and outstanding	—	—
Series A-1 convertible preferred stock, actual — 8,085,108 shares authorized, issued and outstanding; pro forma as adjusted — no shares authorized; no shares issued and outstanding	1	—
Series A-2 convertible preferred stock, actual — 18,060,347 shares authorized; 17,675,347 issued and outstanding; pro forma as adjusted — no shares authorized; no shares issued and outstanding	2	—
Series A-3 convertible preferred stock, actual — 53,870,000 shares authorized, issued and outstanding; pro forma as adjusted — no shares authorized; no shares issued and outstanding	5	—
Common stock, $0.0001 par value; actual — 100,000,000 shares authorized; 2,137,935 shares issued and outstanding; pro forma as adjusted — 100,000,000 shares authorized; 28,045,540 shares issued and outstanding	—	3
Additional paid-in capital	80,525	128,990
Deficit accumulated during the development stage	(45,983)	(45,983)
Total stockholders' equity	34,550	83,010
Total capitalization	$ 40,518	$ 88,978

The number of pro forma as adjusted common shares shown as issued and outstanding in the table is based on the number of shares of our common stock outstanding as of June 30, 2006, and excludes:

- 1,442,372 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2006 at a weighted average exercise price of $1.52 per share;
- 96,250 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2006 at a weighted average exercise price of $4.00 per share; and

- 2,519,693 shares of our common stock reserved for future issuance under our 2006 equity incentive award plan, which will become effective on the day prior to the day on which we become subject to the reporting requirements of the Exchange Act (including 419,693 shares of common stock reserved for future grant or issuance under our 2004 equity incentive award plan, which shares will be added to the shares to be reserved under our 2006 equity incentive award plan).

DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering. As of June 30, 2006, our historical net tangible book value was $34.5 million, or $1.57 per share of common stock. Our historical net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of our common stock outstanding as of June 30, 2006, after giving effect to the conversion of all outstanding shares of our preferred stock into 19,907,605 shares of our common stock. After giving effect to our sale in this offering of 6,000,000 shares of our common stock at the initial public offering price of $9.00 per share and after deducting the underwriting discounts and commissions and estimated offering costs payable by us, our pro forma as adjusted net tangible book value as of June 30, 2006 would have been $83.0 million, or $2.96 per share of our common stock. This represents an immediate increase of net tangible book value of $1.39 per share to our existing stockholders and an immediate dilution of $6.04 per share to investors purchasing shares in this offering. The following table illustrates this per share dilution:

Initial public offering price per share		$ 9.00
Historical net tangible book value per share as of June 30, 2006	$ 1.57	
Increase per share attributable to investors purchasing shares in this offering	1.39	
Pro forma net tangible book value per share, as adjusted to give effect to this offering		2.96
Dilution to investors purchasing shares in this offering		$ 6.04

If the underwriters exercise their overallotment option in full, the pro forma net tangible book value per share after giving effect to this offering would be $3.13 per share, and the dilution in pro forma net tangible book value per share to investors in this offering would be $5.87 per share.

The following table summarizes, as of June 30, 2006, the differences between the number of shares of common stock purchased from us, after giving effect to the conversion of our preferred stock into common stock, the total effective cash consideration paid, and the average price per share paid by our existing stockholders and by our new investors purchasing stock in this offering at the initial public offering price of $9.00 per share before deducting the underwriting discounts and commissions and estimated offering costs payable by us:

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Average Price Per Share
Existing stockholders before this offering	22,045,540	79.0%	$ 79,742,641	60.0%	$ 3.62
Investors purchasing shares in this offering	6,000,000	21.0	54,000,000	40.0	9.00
Total	28,045,540	100.0%	$ 133,742,641	100.0%	$ 4.77

If the underwriters exercise their overallotment option in full, our existing stockholders would own 76% and our new investors would own 24% of the total number of shares of our common stock outstanding after this offering.

The above information assumes no exercise of stock options or warrants outstanding as of June 30, 2006. As of June 30, 2006, there were:

- 1,442,372 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2006 at a weighted average exercise price of $1.52 per share;
- 96,250 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2006 at a weighted average exercise price of $4.00 per share; and
- 2,519,693 shares of our common stock reserved for future issuance under our 2006 equity incentive award plan, which will become effective on the day prior to the day on which we become subject to the reporting requirements of the Exchange Act (including 419,693 shares of common stock reserved for future grant or issuance under our 2004 equity incentive award plan, which shares will be added to the shares to be reserved under our 2006 equity incentive award plan upon the effectiveness of the 2006 equity incentive award plan).

SELECTED FINANCIAL DATA

The following selected statement of operations data for the period from May 26, 2004 (inception) through December 31, 2004, the year ended December 31, 2005 and the balance sheet data as of December 31, 2004 and 2005 have been derived from our audited financial statements included elsewhere in this prospectus. The statement of operations data for the six-month periods ended June 30, 2005 and 2006, the period from May 26, 2004 (inception) through June 30, 2006 and the balance sheet data as of June 30, 2006 have been derived from our unaudited financial statements included elsewhere in this prospectus. The unaudited financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, contain all adjustments, consisting only of normal recurring adjustments, we consider necessary for the fair presentation of the financial data. The selected financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	Period from May 26, 2004 (Inception) Through December 31, 2004	Year Ended December 31, 2005	Six Months Ended June 30,		Period from May 26, 2004 (Inception) Through June 30, 2006
			2005	2006	
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Operating expenses:					
Research and development	$ 1,883	$ 6,126	$ 2,402	$ 33,664	$ 41,674
Marketing	41	240	142	317	598
General and administrative	877	1,412	540	1,968	4,257
Total operating expenses	2,801	7,778	3,084	35,949	46,529
Loss from operations	(2,801)	(7,778)	(3,084)	(35,949)	(46,529)
Other income (expense):					
Interest income	9	255	14	553	818
Interest expense	—	—	—	(44)	(44)
Impairment of investment securities	(45)	(183)	(183)	—	(228)
Total other income	(36)	72	(169)	509	546
Net loss	$ (2,837)	$ (7,706)	$ (3,253)	$ (35,440)	$ (45,983)
Basic and diluted net loss per share(1)	$ (3.10)	$ (6.67)	$ (2.87)	$ (28.50)	
Shares used to compute basic and diluted net loss per share(1)	915	1,156	1,132	1,244	
Pro forma basic and diluted net loss per share(1)		$ (1.49)		$ (2.41)	
Shares used to compute pro forma basic and diluted net loss per share(1)		5,162		14,678	

(1) See Note 1 of Notes to Financial Statements for an explanation of the method used to compute the historical and pro forma net loss per share and the number of shares used in the computation of the per share amounts.

	As of December 31,		As of June 30,
	2004	2005	2006
		(In thousands)	
Balance Sheet Data:			
Cash and cash equivalents and securities available-for-sale	$ 4,271	$ 15,025	$ 42,881
Working capital	4,161	14,405	37,476
Total assets	4,841	15,891	46,477
Long-term debt, less current portion	—	—	5,968
Deficit accumulated during the development stage	(2,837)	(10,543)	(45,983)
Total stockholders' equity	4,727	14,745	34,550

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "Selected Financial Data" and our financial statements and related notes appearing elsewhere in this prospectus. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under "Risk Factors" and elsewhere in this prospectus.

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 Phase III product candidates, both of which have been studied in prior Phase III clinical trials conducted by our licensors. 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. Pending further discussions with the FDA concerning our Phase III development program for IV APAP, we plan to initiate the remaining Phase III clinical trial requirements for this product candidate in the fourth quarter of 2006.

We are a development stage company. We have incurred significant net losses since our inception. As of June 30, 2006, we had an accumulated deficit of $46.0 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.

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. 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 "unallocated" category in the table below.

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

Product Candidate	Period from May 26, 2004 (Inception) Through December 31, 2004	Year Ended December 31, 2005	Six Months Ended June 30, 2005	Six Months Ended June 30, 2006	Period from May 26, 2004 (Inception) Through June 30, 2006
			(In thousands)		
IV APAP	$ —	$ —	$ —	$ 25,698	$ 25,698
Omigard	1,651	4,802	1,850	6,238	12,691
Unallocated	232	1,324	552	1,728	3,285
	$ 1,883	$ 6,126	$ 2,402	$ 33,664	$ 41,674

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, and we have not yet commenced our own Phase III clinical trials for IV APAP. We expect to receive results from the ongoing Omigard clinical trial in the second half of 2007. In the fourth quarter of 2006, we expect to initiate the remaining Phase III clinical trial requirements for IV APAP for submission to the FDA and expect these 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, 2005, we had both federal and state net operating loss carryforwards of approximately $8.7 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, 2005, we had both federal and state research and development tax credit carryforwards of approximately $0.3 million and $0.1 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, who 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 did not result in the recognition of additional stock-based compensation expense.

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 6.06-6.08 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 six months ended June 30, 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 June 30, 2006, we had approximately $7.5 million of unrecognized share-based compensation costs related to nonvested equity awards. As of June 30, 2006, we had outstanding vested options to purchase 85,445 shares of our common stock and unvested options to purchase 1,356,927 shares of our common stock with an intrinsic value of $0.7 million and $10.0 million, respectively, based on the initial public offering price of $9.00 per share.

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.

The fair value of our common stock has been 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 are at an early stage of existence, primarily focused on development with an unproven business model. To date, we have 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. The significant estimates used in the asset-based approach consisted of the valuation of our assets and liabilities, which we determined were substantially the same as their fair market values. Since the fair market value of our net assets, including Omigard development costs incurred, of $22.7 million was less than the $25.3 million liquidation value of our preferred stock, no significant value was assigned to our common stock under the current value method, which allocates value based on liquidation preferences. 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 this 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, 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 that were below the reassessed values. The values of the common stock for May and June of 2006 were initially determined by our board of directors. 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.

In late March 2006, we completed the licensing of IV APAP and completed the sale of our Series A-3 preferred stock of $53.9 million, which was used to acquire the rights to IV APAP and we expect to be used to fund the clinical trials for IV APAP. We believe that the in-license of rights to IV APAP was a significant milestone which resulted in an increase in value since it provided us with a second drug candidate and demonstrated that we could execute on our strategic initiative to have multiple products in clinical trials with the potential for significant future revenues. No other corporate milestones have occurred in 2006 that would result in material changes to our enterprise value. Prior to licensing IV APAP, we did not believe we could enter the public equity markets.

As of March 31, 2006, our board of directors, all of whom are related parties, performed a contemporaneous valuation, which initially resulted in an increase of our common stock valuation to $1.36 per share from $0.40 per share. The valuation utilized a market-based approach for enterprise value and allocated such value to preferred and common stock based on an option pricing model. This approach is consistent with the AICPA guidance based on our stage of development following our in-licensing of rights to IV APAP. The determination of enterprise value was based on our Series A-3 preferred stock financing, in which greater than 50% of the investors consisted of new investors to our company. On May 9, 2006, we granted 1,124,057 stock options at $1.36 per share; however, in connection with our reassessment process, we concluded that with the proximity to the initiation of this offering on June 14, 2006, the value of the options should give more consideration to the expected valuation in this offering. Accordingly, we concluded that the revised fair value of the common stock should be the estimated low end of the preliminary price range for this offering as of June 14, 2006 of $11.00 per share, less a discount for marketability of 40%, which reflects an estimate of the risk of not completing this offering, or $6.60 per share.

On June 12, 2006, we granted 259,500 stock options at $3.20 per share based on a contemporaneous valuation performed by our board of directors. The valuation utilized a market-based approach for enterprise value and allocated such value to preferred and common stock based on an option pricing model. The determination of the enterprise value was based on equal weighting of Series A-3 preferred stock financing values and valuation ranges provided by the underwriters for this offering, less a

marketability discount of 40% determined based on a put option analysis and published data regarding marketability discounts in initial public offerings. However, in connection with our reassessment process and the proximity to the initiation of this offering, management concluded that the value of the options should give more consideration to the expected valuation in this offering. The valuation ranges initially provided by our underwriters are consistent with the current estimates of value contemplated in this offering. Accordingly, the revised fair value of the common stock was estimated to be the low end of the preliminary price range for this offering as of June 14, 2006 of $11.00 per share, less a discount for marketability of 30%, which reflects an estimate of the risk of not completing this offering, or $7.70 per share.

Since we utilized an asset-based approach in our very early stage of development and moved to a market-based approach upon the in-licensing of IV APAP, the probability of successful development of our product candidates was not a specific variable used in our valuation approaches. However, this probability was considered in the price paid for our Series A-3 preferred stock and the valuation ranges provided by the underwriters, which are specific factors included in our valuation approaches.

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.

Results of Operations

Comparison of six months ended June 30, 2006 and 2005

Research and Development Expenses. Research and development expenses increased to $33.7 million for the six months ended June 30, 2006 from $2.4 million for the comparable period during 2005. This increase of $31.3 million primarily was due to:

- an increase of $25.7 million in our IV APAP program primarily as a result of a $25.0 million license fee which was immediately expensed as in-process research and development;
- an increase of $4.4 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 $1.2 million in unallocated expenses as a result of increased salaries and related personnel costs 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 $0.3 million for the six months ended June 30, 2006 from $0.1 million for the comparable period during 2005. This increase of $0.2 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 $2.0 million for the six months ended June 30, 2006 from $0.5 million for the comparable period during 2005. This increase of $1.5 million primarily was due to stock-based compensation charges, legal fees related to the IV APAP license agreement and our new facility lease, other professional fees and consulting fees.

Interest Income. Interest income increased to $553,000 for the six months ended June 30, 2006 from $14,000 for the comparable period during 2005. This increase of $539,000 primarily was due to the increase in average cash and investment balances as a result of preferred stock sales and higher interest rates in 2006.

Interest Expense. Interest expense increased to $44,000 for the six months ended June 30, 2006 from zero for the comparable period during 2005. This increase of $44,000 was primarily due to non-cash

interest expense related to the warrants issued to Silicon Valley Bank and Oxford Finance Corporation in connection with their February 2006 commitment to lend us $7.0 million.

Impairment of Investment Securities. Impairment of investment securities was zero for the six months ended June 30, 2006 compared to $183,000 for the comparable period in 2005. The 2005 impairment charges were 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 $256,000 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 $247,000 primarily was due to the increase in average cash and investment balances and interest rates in 2005.

Impairment of Investment Securities. Impairment of investment securities 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 private placement of equity securities. Through June 30, 2006, we received net proceeds of approximately $79.5 million from the sale of shares of our preferred and common stock as follows:

- from July 2004 to June 2006, we issued and sold a total of 2,137,935 shares of common stock for aggregate net proceeds of $0.6 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.

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 beginning February 2007, we are required to make 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 warrants to the lenders to purchase 385,000 shares of Series A-2 preferred stock at an exercise price of $1.00 per share.

As of June 30, 2006, we had $42.9 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 investments to preserve principal and maintain liquidity.

Our operating activities used net cash in the amount of $31.1 million in the six months ended June 30, 2006, $6.9 million for the year ended December 31, 2005 and $2.7 million for the period from May 26, 2004 (inception) through December 31, 2004. The increase in net cash used in operating activities from 2004 to 2005 primarily was due to an increase in our net loss as a result of increased expenses related to the clinical development of Omigard and increased salaries and overhead of company personnel. 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 expenses related to the 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 involved in enforcing or defending patent claims or other intellectual property rights;
- the costs and timing of regulatory approvals;
- 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 will be sufficient to meet our projected operating requirements through at least June 30, 2007.

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, 2005:

	Payments Due by Period				
	Total	Less Than 1 Year	1 - 3 Years	4-5 Years	After 5 Years
			(In thousands)		
Long-term debt obligations(1)	$ —	$ —	$ —	$ —	$ —
Operating lease obligations(2)	147	147	—	—	—
License obligations(3)	—	—	—	—	—
Total	$ 147	$ 147	$ —	$ —	$ —

(1) Long-term debt obligations do not include $7.0 million of indebtedness incurred in June 2006 under our loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation.

(2) In May 2006, we entered into a six-year operating lease for 23,494 square feet of office space. Operating lease obligations do not include $6.7 million of non-cancelable operating lease payments related to this lease. Future minimum payments under the operating lease total $0.2 million, $1.0 million, $1.1 million, $1.1 million, $1.2 million, $1.2 million and $0.9 million for the years ending December 31, 2006, 2007, 2008, 2009, 2010, 2011 and 2012, respectively.

(3) 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.

Related Party Transactions

For a description of our related party transactions, see the "Certain Relationships and Related Party Transactions" section of this prospectus.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities.

Quantitative and Qualitative Disclosures About Market Risk

Our cash and cash equivalents as of June 30, 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, particularly because the majority of our investments are in short-term marketable securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities 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 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 our investment will probably decline. To minimize this risk, we intend to continue to maintain our portfolio of cash equivalents and short-term investments 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.

BUSINESS

Overview

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 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 intend to initiate Phase III development for the treatment of acute pain in the fourth quarter of 2006 and 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 the results observed for the prevention of 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 four years. Since its introduction in Europe in mid-2002, over 100 million doses of IV APAP have been administered to patients, and it has become the market share leader among injectable analgesics with 2005 sales of more than $140 million according to IMS. With approval in over 40 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 expect to initiate the remaining Phase III clinical trial requirements. We expect these Phase III clinical trial results to be available in the first half of 2008 and, if positive, to subsequently submit 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 the 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 cleanse the skin surface around the catheter insertion site prior to insertion. 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 the prevention of LCSIs and 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 received through the special protocol assessment, or SPA, process. We expect these Phase III results to be available in the second half of 2007 and 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,

we plan to resume a U.S. Phase III program later this year for IV APAP previously initiated by BMS, and we expect to submit an NDA in the second half of 2008 based on the previously completed trials 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 13 U.S. states that require hospitals to publicly report their infections rates and there are more than 20 other states that have had legislative activity related to public reporting of infection rates in 2006. 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 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 expect to initiate the remaining Phase III clinical trial requirements for submission in the United States. We expect these 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 251 million vials in 2005. Morphine is the current market leader and accounted for more than 135 million vials in 2005. Other injectable opioids such as meperidine, hydromorphone and fentanyl, which are all available in generic forms, accounted for more than 80 million vials in 2005. 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 33 million vials in 2005.

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 injectable 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 normal range of 98.6 degrees Fahrenheit. A significant fever is usually defined as an oral or ear temperature of greater than 102 degrees Fahrenheit or a rectal temperature of greater than 103 degrees Fahrenheit. Very high fevers may cause hallucinations, confusion, irritability, convulsions or death. Fever is most often an important immune system response to a viral or bacterial infection since most viruses and bacteria cannot thrive in hot environments. White blood cells release substances called pyrogens that act on the hypothalamus in the brain to raise body temperature.

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

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 40 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 43% dollar share (20% vial share) as of the first quarter of 2006. In 2005, IV APAP sold more than 55 million vials, which represents a 21% increase over 2004 according to IMS. Total sales of IV APAP exceeded $140 million (U.S. dollars) in 2005 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.

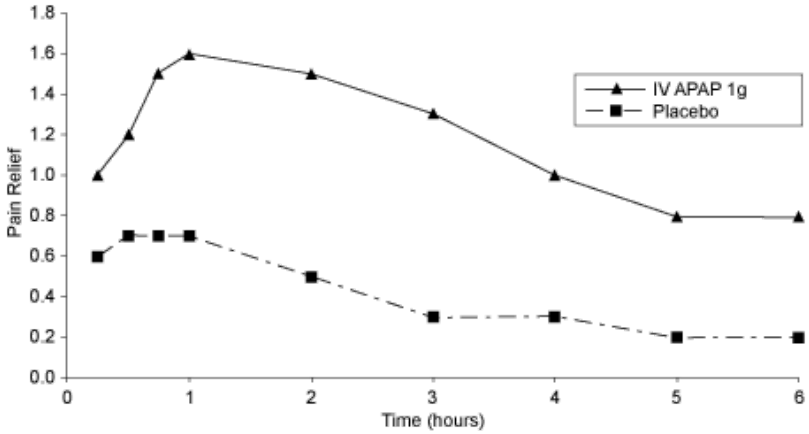
Clinical Development History

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 150 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 ($p\text{-value} < 0.05$) 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. 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 well-understood and occurs rarely when acetaminophen is dosed in accordance with the recommended guidelines. In addition, an effective antidote, N-acetylcysteine, is available to treat acetaminophen overdose. We believe 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. This is also consistent with observations from the European post-marketing safety database of IV APAP which covers a time period in which over 100 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 study to assess the efficacy and safety of single and multiple doses of IV APAP.

- 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.
- Pharmacokinetic study in pediatric 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 children.
- Safety study in adult subjects: this trial will be an open-label, multi-center study to assess the safety of single and multiple doses of IV APAP in adults.
- Safety study in pediatric subjects: this trial will be an open-label, multi-center study to assess the safety of single and multiple doses of IV APAP in children.

Total enrollment of the six clinical trials is expected to be approximately 750 subjects. We intend to initiate the gynecologic surgery Phase III trial and 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 Colorado, Connecticut, Florida, Illinois, Maryland, Missouri, New Hampshire, New York, Pennsylvania, South Carolina, Tennessee, Vermont and Virginia. In 2006, more than 20 other states have had some legislative activity related to public reporting of hospital-acquired infections. We believe that the increased scrutiny on catheter-related infections in addition to compelling economic incentives will drive adoption of new products which show an ability to reduce infection rates.

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 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 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 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 delivers chlorhexidine to 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;
- 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 vancomycin-resistant *enterococcus*, or 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 the topical antiseptics, 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 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 not 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 in a total of 273 subjects. These trials demonstrated no evidence of sensitization, clinically significant irritation or systemic absorption. In addition, the Phase I trial exhibited killing of greater than 99.9% of bacteria and fungi on skin and maintained this level of antimicrobial activity for at least three days.

Migenix 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 a statistically significant prevention in 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 a statistically significant prevention in LCSI (*p-value*=0.004). The table below summarizes data for LCSI in the modified intent-to-treat analysis set, which includes only those 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 an LCSI and a catheter removed (*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

Despite these favorable, statistically significant results for the prevention of LCSI and catheter colonization, 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.

	Treatment Arm		
Outcome	**10% povidone-iodine**	**Omigard**	**p-value**
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 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, the high rate of indeterminate events was observed, 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 the number of patients enrolled.

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 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. Omigard for the prevention of LCSIs was awarded fast track status by the FDA, and we intend 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 initially be used in combination with topical antiseptics but ultimately may be used as a stand-alone treatment after more widespread use. We intend to initially target Omigard to high risk patients we believe, based on market research, to 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 were 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, currently marketed by Endo Pharmaceuticals, is an extended release injectable 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 June 30, 2006, we had 24 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.

Facilities

We lease approximately 23,494 square feet of space in our headquarters in San Diego, California under a sublease that expires in 2012. We intend to sublease approximately 5,800 square feet of our headquarters for a period of two years. 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.

Legal Proceedings

We are not engaged in any legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information about our executive officers and directors as of September 30, 2006:

Name	Age	Position
Theodore R. Schroeder	51	President, Chief Executive Officer and Director
James B. Breitmeyer, M.D., Ph.D.	52	Executive Vice President, Development and Chief Medical Officer
William S. Craig, Ph.D.	56	Senior Vice President, Pharmaceutical Development and Manufacturing
William R. LaRue	55	Senior Vice President, Chief Financial Officer, Treasurer and Secretary
Richard E. Lowenthal	40	Vice President, Regulatory Affairs and Quality Assurance
Mike A. Royal, M.D., J.D.	53	Vice President, Clinical Development, Analgesics
David A. Socks	32	Vice President, Business Development
Cam L. Garner(1)	58	Chairman of the Board of Directors
Brian G. Atwood(2)	53	Director
Samuel L. Barker, Ph.D.	64	Director
Michael A. Berman, M.D.(2)(3)	64	Director
James C. Blair, Ph.D.(1)	67	Director
Alan D. Frazier(1)(3)	55	Director
Alain B. Schreiber, M.D.(2)	51	Director
Christopher J. Twomey(3)	47	Director

(1) Member of the Compensation Committee.
(2) Member of the Nominating/ Corporate Governance Committee.
(3) Member of the Audit Committee.

Executive Officers

Theodore R. Schroeder is one of our co-founders and has served as our President and Chief Executive Officer and as a member of our board of directors since our inception in May 2004. From August 2002 to February 2004, he served as Senior Vice President of North America Sales and Marketing of Elan Pharmaceuticals, Inc., a neuroscience-based pharmaceutical company. From February 2001 to August 2002, Mr. Schroeder served as General Manager of the Hospital Products Business Unit at Elan, a position he also held at Dura Pharmaceuticals, Inc., a specialty respiratory pharmaceutical and pulmonary drug delivery company, from May 1999 to November 2000 until its acquisition by Elan. Prior to joining Dura, Mr. Schroeder held a number of hospital-related sales and marketing positions with Bristol-Myers Squibb Company, a global pharmaceutical company. Mr. Schroeder holds a B.S. in management from Rutgers University.

James B. Breitmeyer, M.D., Ph.D. has served as our Executive Vice President, Development and Chief Medical Officer since August 2006. From December 2001 to August 2006, Dr. Breitmeyer served as Chief Medical Officer and Vice President, Pharmaceutical Operations of Applied Molecular Evolution, a wholly-owned subsidiary of Eli Lilly and Company, a global pharmaceutical company. From February 2000 to July 2001, Dr. Breitmeyer was the President and Chief Executive Officer of the Harvard Clinical Research Institute. Prior to February 2000, Dr. Breitmeyer held various positions of increasing

responsibility including Senior Vice President and Chief Medical Officer of Serono International S.A., a global biopharmaceutical company. Dr. Breitmeyer holds a B.A. in chemistry from the University of California, Santa Cruz, and an M.D. and Ph.D. from Washington University School of Medicine.

William S. Craig, Ph.D. has served as our Senior Vice President, Pharmaceutical Development and Manufacturing since November 2004. From January 2000 to November 2004, Dr. Craig served as Vice President, Research and Product Development of ISTA Pharmaceuticals, Inc., an ophthalmology-focused specialty pharmaceutical company. From 1996 to December 1999, Dr. Craig served as Vice President, Research and Development for Alpha Therapeutics Corporation, a biotechnology company. From 1988 to 1996, he served as Senior Director, Research and Development for Telios Pharmaceuticals, Inc., a biotechnology company. Dr. Craig holds a B.S. in biochemistry from the University of Michigan and a Ph.D. in chemistry from the University of California, San Diego.

William R. LaRue has served as our Senior Vice President, Chief Financial Officer, Treasurer and Secretary since June 2006. From April 2001 to May 2006, Mr. LaRue served as Senior Vice President and Chief Financial Officer of Micromet, Inc., formerly CancerVax Corporation, a biotechnology company focused on the treatment and control of cancer. From March 2000 to February 2001, Mr. LaRue served as Executive Vice President and Chief Financial Officer of eHelp Corporation, a provider of user assistance software. From January 1997 to February 2000, Mr. LaRue served as Vice President and Treasurer of Safeskin Corporation, a medical device company, and from January 1993 to January 1997 he served as Treasurer of GDE Systems, Inc., a high technology electronic systems company. Mr. LaRue received a B.S. in business administration and an M.B.A. from the University of Southern California.

Richard E. Lowenthal has served as our Vice President, Regulatory Affairs and Quality Assurance since November 2004. From November 2002 to November 2004, Mr. Lowenthal served as Head, Worldwide Regulatory Affairs and Drug Safety of Maxim Pharmaceuticals, Inc., a biopharmaceutical company. From December 2001 to November 2002, he served as Vice President of Regulatory Affairs and Quality Assurance of AnGes, MG, Inc., a biotechnology company. From June 1996 to December 2001, Mr. Lowenthal served in various roles in regulatory affairs and research and development at Janssen Research Foundation, a division of Johnson & Johnson, including Global Project Leader for Risperdal New Products and most recently as the Global Director of Chemistry, Manufacturing and Control Regulatory Affairs. From March 1995 to June 1996, he served as the Director of Regulatory Affairs and Quality Assurance of Somerset Pharmaceuticals, Inc., a proprietary research and development pharmaceutical company. Prior to joining Somerset, Mr. Lowenthal worked at the FDA as a new drug reviewer in the Division of Neuropharmacologic Drug Products and in the Division of Oncology and Pulmonary Drug Products. Mr. Lowenthal holds a B.Sc. in biochemistry from Florida State University, an M.Sc. in organic chemistry from Florida State University and a Masters of Business Science in Executive Leadership from the University of San Diego.

Mike A. Royal, M.D., J.D. has served as our Vice President, Clinical Development, Analgesics since April 2006. From December 2004 to March 2006, Dr. Royal served as Chief Medical Officer of Solstice Neurosciences, Inc., a specialty biopharmaceutical company. From May 2003 to December 2004, Dr. Royal served as Vice President, Strategic Brand Development and Global Medical Affairs of Alpharma Inc., a global specialty pharmaceutical company. From January 2002 to May 2003, he served as Senior Medical Director of Elan Pharmaceuticals, Inc., a neuroscience-based biotechnology company. From 1994 to January 2002, he owned and managed the largest private practice pain management clinic and research center in Oklahoma. Dr. Royal has also served as Director of the Acute Pain Service, Staff Anesthesiologist, and Assistant Professor of Anesthesiology and Critical Care Medicine at the University of Pittsburgh Medical Center. Dr. Royal is board certified in internal medicine, anesthesiology, pain management, and addiction medicine and has published extensively in the area of pain management. He holds a B.S. in chemistry from the Massachusetts Institute of Technology, an M.D. from the University of Massachusetts, a J.D. from the University of Maryland and an M.B.A. from New York University (TRIUM).

David A. Socks is one of our co-founders and has served as our Vice President, Business Development since our inception in May 2004. From May 2004 to June 2006, Mr. Socks also served as our Chief Financial Officer, Treasurer, and Secretary. From July 2000 to May 2004, Mr. Socks was a Venture Partner at Windamere Venture Partners, a venture capital firm investing in early stage life science companies. In this capacity, Mr. Socks held management positions at two portfolio companies of Windamere Venture Partners. These positions included Vice President of Business Development of Kanisa Pharmaceuticals, Inc., an oncology-focused specialty pharmaceutical company and Vice President of Finance of CelTor Biosystems, Inc., a drug discovery company. Mr. Socks co-founded several pharmaceutical companies including Avera Pharmaceuticals, Inc., Kanisa Pharmaceuticals, Inc., Somaxon Pharmaceuticals, Inc. and Verus Pharmaceuticals, Inc. and two medical technology companies including MiraMedica, Inc. and SpineWave, Inc. In 1999, Mr. Socks worked in business development at Neurocrine Biosciences, a biopharmaceutical company. In 1998, he worked in the venture capital arm of EFO Holdings, L.P., an investment firm. From 1995 to 1998, he worked at Kaiser Associates, Inc., a strategic management consulting firm, where he was most recently a Senior Manager. Mr. Socks holds a B.S. in business administration from Georgetown University and an M.B.A. from Stanford University.

Board of Directors

Cam L. Garner is one of our co-founders and has served as a member of our board of directors since our inception in May 2004, and as the chairman of our board of directors since July 2004. Mr. Garner co-founded Verus Pharmaceuticals, Inc., Somaxon Pharmaceuticals, Inc. and Xcel Pharmaceuticals, Inc., which are specialty pharmaceutical companies. Since July 2004, he has served as Chairman and Chief Executive Officer of Verus. He served as Chairman of Xcel Pharmaceuticals, Inc. from January 2001 until it was acquired in March 2005 by Valeant Pharmaceuticals International. From August 2001 to February 2002, he served as acting Chief Executive Officer of Favrille, Inc., a biotechnology company, and is currently the Chairman of its board of directors. From 1989 to 1995, he served as Chief Executive Officer of Dura Pharmaceuticals, Inc., a specialty respiratory pharmaceutical and pulmonary drug delivery company, and Chairman and Chief Executive Officer from 1995 to 2000 until it was sold to Elan in November 2000. Previously, he served as Chairman of DJ Pharma, a specialty pharmaceutical sales and marketing company, which was sold to Biovail Corporation in 2000. Mr. Garner serves as chairman of the board of Favrille, Inc., a biopharmaceutical company, and also serves on the board of directors of two other publicly-held companies — Somaxon Pharmaceuticals, Inc., a specialty pharmaceutical company, and Pharmion Corporation, a biotechnology company — and other privately-held pharmaceutical companies. In addition, Mr. Garner participates on the boards of several charitable organizations. Mr. Garner holds a B.A. in biology and an M.B.A. from Baldwin-Wallace College and an honorary Doctor of Science from Virginia Wesleyan College.

Brian G. Atwood has served as a member of our board of directors since March 2006. Since 1999, Mr. Atwood has served as a Managing Director of Versant Ventures I, LLC, Versant Ventures II, LLC and Versant Ventures III, LLC (Versant Ventures), a venture capital firm focusing on healthcare that he co-founded. Prior to founding Versant Ventures, Mr. Atwood served as a general partner of Brentwood Associates, a venture capital firm. Mr. Atwood also serves on the board of directors of Pharmion Corporation, ForteBio, FivePrime Therapeutics, Inc., Saegis Pharmaceuticals, Helicos Biosciences Corp. and Spaltudaq Corporation. Mr. Atwood holds a B.S. in biological sciences from the University of California, Irvine, an M.S. in ecology from the University of California, Davis and an M.B.A. from Harvard University.

Samuel L. Barker, Ph.D. has served as a member of our board of directors since August 2006. In March 2001, Dr. Barker co-founded Clearview Projects, Inc., a provider of partnering and transaction services to biopharmaceutical companies, and has served as a principal since that time. Dr. Barker also served as President and Chief Executive Officer of Clearview Projects from July 2003 to November 2004. Dr. Barker served in a series of leadership positions at Bristol-Myers Squibb Company until his retirement in 1999. His positions at Bristol-Myers Squibb included service as Executive Vice President, Worldwide Franchise Management and Strategy during 1998, President, United States Pharmaceuticals from 1992 to

1997, and President, Bristol-Myers Squibb Intercontinental Commercial Operations from 1990 to 1992. Prior to 1990, Dr. Barker held executive positions in research and development, manufacturing, finance, business development and sales and marketing at Squibb Pharmaceuticals. Dr. Barker also serves on the board of directors of AtheroGenics, Inc., a pharmaceutical company, and Lexicon Genetics Incorporated, a biopharmaceutical company, where he serves as chairman. Dr. Barker holds a B.S. from Henderson State College, an M.S. from the University of Arkansas and a Ph.D. from Purdue University.

Michael A. Berman, M.D. has served as a member of our board of directors since April 2006. Since January 2005, Dr. Berman has served as President and Chief Executive Officer of the Michael A. Berman Group, Inc., a consulting firm specializing in the healthcare industry. Since January 2005, Dr. Berman has also served as a consultant for Stockamp and Associates, Inc., a business process consulting firm specializing in the healthcare industry. From October 1999 to January 2005, Dr. Berman served as Executive Vice President and Director of New York Presbyterian Hospital, and from September 1997 to October 1999 as its Senior Vice President and Chief Medical Officer. From April 1984 to September 1997, he served as Professor and Chairman of the Department of Pediatrics at the University of Maryland School of Medicine. Dr. Berman holds a M.D. from the State University of New York, Syracuse.

James C. Blair, Ph.D. has served as a member of our board of directors since September 2005. Since 1985, Mr. Blair has been a partner of Domain Associates, L.L.C., a venture capital management company focused on life sciences. Mr. Blair also serves on the board of directors of Cell Biosciences, Inc., Five Prime Therapeutics, Inc., GenVault Corporation, NeuroPace, Inc., Novacea, Inc., NuVasive, Inc., Pharmion Corporation, Verus Pharmaceuticals, Inc. and Volcano Corporation. Mr. Blair has over 35 years experience with venture and emerging growth companies. In the course of this experience, he has been involved in the creation and successful development at the board level of over forty life science ventures, including Amgen Inc., Aurora Biosciences Corporation, Amylin Pharmaceuticals, Inc., Applied Biosystems Inc., Dura Pharmaceuticals, GeneOhm Sciences, Inc. and Molecular Dynamics Inc. A former managing director of Rothschild Inc., Mr. Blair was directly involved at a senior level with Rothschild/ New Court venture capital activities from 1978 to 1985. From 1969 to 1978, he was associated with F.S. Smithers and Co. and White, Weld and Co., two investment banking firms actively involved with new ventures and emerging growth companies. From 1961 to 1969, Mr. Blair was an engineering manager with RCA Corporation, during which time he received a David Sarnoff Fellowship. He currently serves on the board of directors of the Prostate Cancer Foundation, a philanthropic organization, and he is on the advisory boards of the Department of Molecular Biology at Princeton University and the Department of Biomedical Engineering at the University of Pennsylvania. Mr. Blair holds a B.S.E. from Princeton University and an M.S.E. and Ph.D. from the University of Pennsylvania.

Alan D. Frazier has served as a member of our board of directors since March 2006. In 1991, Mr. Frazier founded Frazier Healthcare Ventures, a venture capital firm, and has served as the managing partner since its inception. From 1983 to 1991, Mr. Frazier served as Executive Vice President, Chief Financial Officer and Treasurer of Immunex Corporation, a biopharmaceutical company. From 1980 to 1983, Mr. Frazier was a principal in the Audit Department of Arthur Young & Company, which is now Ernst & Young LLP. Mr. Frazier is a member of the board of directors of Alexza Pharmaceuticals, Inc., a pharmaceutical company. Mr. Frazier received a B.A. in economics from the University of Washington.

Alain B. Schreiber, M.D. has served as a member of our board of directors since July 2004. Since 2000, Dr. Schreiber has been a General Partner of ProQuest Investments, a venture capital firm. From May 1992 to June 2000, Dr. Schreiber served as President, Chief Executive Officer and a director of Vical Incorporated, a biopharmaceutical company. From July 1985 to April 1992, he held various positions with Rhone-Poulenc Rorer Inc., which is now Sanofi-Aventis, most recently as Senior Vice President of Discovery Research. From October 1982 to June 1985, Dr. Schreiber served as Biochemistry Department Head at Syntex Research, which is now Roche Bioscience. Dr. Schreiber currently serves on the board of several privately held companies including BioRexis Pharmaceutical Corporation, Concentric Medical, Inc.

and Optimer Pharmaceuticals, Inc. Dr. Schreiber holds a B.S. in chemistry and an M.D. from the Free University in Brussels, Belgium.

Christopher J. Twomey has served as a member of our board of directors since July 2006. Mr. Twomey joined Biosite Incorporated, a medical diagnostic company, in March 1990 and is currently its Senior Vice President, Finance and Chief Financial Officer. From 1981 to 1990, Mr. Twomey worked for Ernst & Young LLP, where he served as an Audit Manager. Mr. Twomey also serves on the board of directors of Senomyx, Inc., a biotechnology company, where he serves as Chair of the Audit Committee. Mr. Twomey holds a B.A. in business economics from the University of California at Santa Barbara.

Board Composition

Our board of directors is currently authorized to have eight members, and is currently composed of seven non-employee members and our current President and Chief Executive Officer, Theodore R. Schroeder. Upon completion of this offering, our amended and restated certificate of incorporation will provide for a classified board of directors consisting of three classes of directors, each serving staggered three-year terms. As a result, a portion of our board of directors will be elected each year. To implement the classified structure, prior to the consummation of this offering, two of the nominees to the board will be appointed to one-year terms, three will be appointed to two-year terms and three will be appointed to three-year terms. Thereafter, directors will be elected for three-year terms. Our Class I directors, whose terms will expire at the 2007 annual meeting of stockholders, will be Drs. Berman and Schreiber and Mr. Schroeder. Our Class II directors, whose terms will expire at the 2008 annual meeting of stockholders, will be Dr. Blair and Messrs. Frazier and Twomey. Our Class III directors, whose terms will expire at the 2009 annual meeting of stockholders, will be Dr. Barker and Messrs. Atwood and Garner.

Pursuant to a voting agreement originally entered into in July 2004 and most recently amended in August 2006 by and among us and certain of our stockholders, Drs. Barker, Berman, Blair and Schreiber and Messrs. Atwood, Frazier, Garner, Schroeder and Twomey were each elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve. The voting agreement will terminate upon completion of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until their successors are duly elected by holders of our common stock. For a more complete description of the voting agreement, see “Certain Relationships and Related Party Transactions — Voting Agreement.”

Board Committees

Our board of directors has established three committees: the audit committee, the compensation committee and the nominating/corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business.

Audit Committee. Our audit committee consists of Messrs. Twomey (chair and audit committee financial expert) and Frazier and Dr. Berman, each of whom our board of directors has determined is independent within the meaning of the independent director standards of the SEC and the Nasdaq Stock Market, Inc.

This committee’s main function is to oversee our accounting and financial reporting processes, internal systems of control, independent registered public accounting firm relationships and the audits of our financial statements. This committee’s responsibilities include:

- selecting and hiring our independent registered public accounting firm;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;

- reviewing the design, implementation, adequacy and effectiveness of our internal controls and our critical accounting policies;
- overseeing and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding our results of operations;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics.

Compensation Committee. Our compensation committee consists of Messrs. Garner (chair) and Frazier and Dr. Blair, each of whom our board of directors has determined is independent within the meaning of the independent director standards of the Nasdaq Stock Market, Inc. This committee's purpose is to assist our board of directors in determining the development plans and compensation for our senior management and directors and recommend these plans to our board. This committee's responsibilities include:

- reviewing and recommending compensation and benefit plans for our executive officers and compensation policies for members of our board of directors and board committees;
- reviewing the terms of offer letters and employment agreements and arrangements with our officers;
- setting performance goals for our officers and reviewing their performance against these goals;
- evaluating the competitiveness of our executive compensation plans and periodically reviewing executive succession plans; and
- preparing the report that the SEC requires in our annual proxy statement.

Nominating/ Corporate Governance Committee. Our nominating/corporate governance committee consists of Mr. Atwood (chair) and Drs. Berman and Schreiber, each of whom our board of directors has determined is independent within the meaning of the independent director standards of the Nasdaq Stock Market, Inc. This committee's purpose is to assist our board by identifying individuals qualified to become members of our board of directors, consistent with criteria set by our board, and to develop our corporate governance principles. This committee's responsibilities include:

- evaluating the composition, size and governance of our board of directors and its committees and making recommendations regarding future planning and the appointment of directors to our committees;
- administering a policy for considering stockholder nominees for election to our board of directors;
- evaluating and recommending candidates for election to our board of directors;
- overseeing our board of directors' performance and self-evaluation process; and
- reviewing our corporate governance principles and providing recommendations to the board regarding possible changes.

Compensation Committee Interlocks and Insider Participation

Prior to establishing the compensation committee, our board of directors as a whole performed the functions delegated to the compensation committee. None of the members of our compensation committee

has ever been one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Director Compensation

From September 2004 through August 2005, we paid Mr. Garner $5,000 per month plus qualified business expenses for his services as chairman of our board of directors under the terms of a consulting agreement between us and a limited liability company affiliated with Mr. Garner. The agreement expired on August 31, 2005. From September 2005 to February 2006, we continued to pay Mr. Garner $5,000 per month for his services as chairman of our board of directors. In February 2006, Mr. Garner's monthly compensation for his services as chairman of our board of directors was increased to $8,333 per month.

Other than to Mr. Garner, we have historically not provided cash compensation to directors for their services as directors or members of committees of the board of directors. Following the completion of this offering, we intend to provide cash compensation in the form of an annual retainer of $25,000 for each non-employee director. We will also pay an additional annual retainer to the non-employee director serving as (i) the chairman of our Audit Committee equal to $10,000, and (ii) the chairman of our Compensation Committee or our Nominating/ Corporate Governance Committee equal to $4,000. We will pay an additional annual retainer to non-employee directors (other than the chairman) serving on the Audit Committee equal to $5,000 and to non-employee directors (other than the chairman) serving on the Compensation Committee or the Nominating/Corporate Governance Committee equal to $2,000. We will pay additional cash compensation to the non-employee director serving as the chairman of our board of directors equal to $100,000 per year. We have reimbursed and will continue to reimburse our non-employee directors for their reasonable expenses incurred in attending meetings of our board of directors and committees of the board of directors.

Following the completion of this offering, any non-employee director who is first elected to the board of directors will be granted a non-qualified option to purchase 25,000 shares of our common stock (subject to adjustment as provided in the 2006 plan described below) on the date of his or her initial election to the board of directors. Such options will have an exercise price per share equal to the fair market value of our common stock on the date of grant. In addition, on the date of each annual meeting of our stockholders following this offering, each non-employee director will be eligible to receive a non-qualified option to purchase 12,500 shares of common stock (subject to adjustment as provided in the 2006 plan described below).

The initial options granted to non-employee directors described above will vest in thirty-six (36) equal monthly installments on the first day of each calendar month subsequent to the date of grant, subject to the director's continuing service on our board of directors on those dates. The annual options granted to non-employee directors described above will vest in twelve equal monthly installments on the first day of each calendar month following the date of grant, subject to the director's continuing service on our board of directors on those dates. The term of each option granted to a non-employee director shall be ten years. The terms of these options are described in more detail under "— Employee Benefit and Stock Plans."

Executive Compensation

The following table summarizes the compensation that we paid to our Chief Executive Officer and each of our four other most highly compensated executive officers during the year ended December 31, 2005. We refer to these officers in this prospectus as our named executive officers.

Summary Compensation Table

Name and Principal Position	Annual Compensation		Other Annual Compensation	Long-Term Compensation	All Other Compensation
	Salary	Bonus		Securities Underlying Options	
Named Executive Officers					
Theodore R. Schroeder *President and Chief Executive Officer*	$ 250,000	$ 30,000	—	62,500	—
Richard E. Lowenthal *Vice President, Regulatory Affairs and Quality Assurance*	220,000	25,430	—	141,000	—
William S. Craig, Ph.D. *Senior Vice President, Pharmaceutical Development and Manufacturing*	220,000	23,161	—	87,500	—
Kenneth R. Heilbrunn, M.D.(1) *Senior Vice President, Clinical Development*	206,250	6,000	—	87,500	—
David A. Socks *Vice President, Business Development*	175,000	10,000	—	—	—

(1) Dr. Heilbrunn joined us as our Senior Vice President, Clinical Development in April 2005 and, therefore, the amounts set forth above reflect less than a full year. Effective September 30, 2006, Dr. Heilbrunn resigned.

In May 2006, Dr. Mike A. Royal, M.D., J.D. joined us as our Vice President, Clinical Development, Analgesics at an annual salary of $275,000. In June 2006, Mr. William R. LaRue joined us as our Senior Vice President, Chief Financial Officer, Treasurer and Secretary at an annual salary of $265,000. In August 2006, Dr. James B. Breitmeyer joined us as our Executive Vice President, Development and Chief Medical Officer at an annual salary of $330,000.

Option Grants in Last Fiscal Year

The following table sets forth certain information with respect to stock options granted to the individuals named in the Summary Compensation Table during the fiscal year ended December 31, 2005, including the potential realizable value over the ten-year term of the options, based on assumed rates of stock appreciation of 5% and 10%, compounded annually, minus the applicable per share exercise price.

These assumed rates of appreciation are mandated by the rules of the SEC and do not represent our estimate or projection of our future common stock price. We cannot assure you that any of the values in the table will be achieved. Actual gains, if any, on stock option exercises will be dependent on the future performance of our common stock and overall stock market conditions. The assumed 5% and 10% rates of stock appreciation are based on the initial public offering price of $9.00 per share. The percentage

of total options granted is based upon our granting of options to employees, directors and consultants in 2005 to purchase an aggregate of 769,250 shares of our common stock.

	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term	
Name	Number of Shares Underlying Options Granted	% of Total Options Granted to Employees In Last Fiscal Year	Exercise Price Per Share	Expiration Date	5%	10%
Theodore R. Schroeder	62,500	8.12%	$ 0.40	12-29-2015	$ 891,253	$ 1,433,980
Richard E. Lowenthal	75,000	9.75	0.40	2-15-2015	1,069,504	1,720,776
	66,000	8.58	0.40	12-29-2015	941,163	1,514,283
William S. Craig, Ph.D.	87,500	11.37	0.40	2-15-2015	1,247,755	2,007,572
Kenneth R. Heilbrunn, M.D.(1)	87,500	11.37	0.40	5-19-2015	1,247,755	2,007,572
David A. Socks	—	—	—	—	—	—

(1) Effective September 30, 2006, Dr. Heilbrunn resigned as our Senior Vice President, Clinical Development.

Aggregate Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

The following table describes for the named executive officers the number and value of securities underlying exercisable and unexercisable options held by them as of December 31, 2005. The value realized and the value of unexercised in-the-money options at December 31, 2005 are based on the initial public offering price of $9.00 per share less the per share exercise price, multiplied by the number of shares issued or issuable, as the case may be, upon exercise of the option. All options were granted under our 2004 equity incentive award plan.

			Number of Securities Underlying Unexercised Options at December 31, 2005		Value of Unexercised In-the-Money Options at December 31, 2005	
Name	Number of Shares Acquired on Exercise	Value Realized	Exercisable	Unexercisable	Exercisable	Unexercisable
Theodore R. Schroeder	250,000(1)	$ 2,150,000	—	—	$ —	$ —
Richard E. Lowenthal	141,000(2)	1,212,600	—	—		
William S. Craig, Ph.D.	—		87,500(3)	—	752,500	—
Kenneth R. Heilbrunn, M.D.	—		87,500(4)	—	752,500	—
David A. Socks	—		25,000(5)	—	215,000	—

(1) Of these 250,000 shares, 191,406 were unvested as of December 31, 2005.

(2) Of these 141,000 shares, 122,250 were unvested as of December 31, 2005.

(3) Of these 87,500 shares, 63,802 were unvested as of December 31, 2005.

(4) Of these 87,500 shares, 87,500 were unvested as of December 31, 2005. Effective September 30, 2006, Dr. Heilbrunn resigned as our Senior Vice President, Clinical Development, at which time the vesting of options to purchase 48,437 shares of our common stock was accelerated.

(5) Of these 25,000 shares, 17,188 were unvested as of December 31, 2005.

Employment Agreements

We have entered into employment agreements with Theodore R. Schroeder, our President and Chief Executive Officer, James B. Breitmeyer, M.D., Ph.D., our Executive Vice President, Development and Chief Medical Officer, William S. Craig, Ph.D., our Senior Vice President, Pharmaceutical Development and Manufacturing, William R. LaRue, our Senior Vice President, Chief Financial Officer, Treasurer and Secretary, Richard E. Lowenthal, our Vice President, Regulatory Affairs and Quality Assurance, Mike A. Royal, M.D., J.D., our Vice President, Clinical Development, Analgesics, and David A. Socks, our Vice President, Business Development.

Pursuant to the employment agreements, each executive is required to faithfully, industriously and to the best of his or her ability, experience and talent perform all of the duties that may be assigned to such executive pursuant to his or her employment agreement, and shall devote substantially all of his or her productive time and efforts to the performance of such duties.

The base salaries of the executives are set forth in the employment agreements. The employment agreements do not provide for automatic annual increases in salary, but each employment agreement provides for annual salary reviews. The employment agreements provide that each executive shall participate in any bonus plan that our board of directors or its designee may approve for our senior executives (see "— Employee Benefit and Stock Plans — Annual Bonus Plan" below). Each executive's employment is at-will and may be terminated by us at any time, with or without notice. Similarly, each executive may terminate his or her employment with us at any time, with or without notice.

The employment agreements provide each executive with certain severance benefits in the event his or her employment is terminated as a result of his or her death or permanent disability. Specifically, in the event of such a termination, each executive will receive any accrued but unpaid base salary as of the date of termination, a lump sum cash payment equal to the executive's annual base salary, and a lump sum cash payment equal to the executive's prorated annual bonus. Additionally, in the event of an executive's death, his or her eligible dependents would receive 12 months healthcare benefits continuation coverage at our expense. In the event of an executive's permanent disability, he or she will receive 12 months healthcare and life insurance benefits continuation at our expense.

The employment agreements also provide each executive with certain severance benefits in the event his or her employment is terminated by us other than for "cause", as defined in the agreements and described below, or if the executive resigns with "good reason", as defined in the agreements and described below. Specifically, if such termination occurs within three months prior to or within 12 months following a change of control, each executive will receive any accrued but unpaid base salary as of the date of termination, a lump sum cash payment equal to the executive's annual base salary, a lump sum cash payment equal to the executive's prorated annual bonus, and 12 months healthcare and life insurance benefits continuation coverage at our expense, plus a maximum of $15,000 towards outplacement services. If such termination occurs more than three months prior to a change of control or more than 12 months following a change of control, each executive will receive the benefits described in the previous sentence, less the prorated annual bonus.

The employment agreements provide that, in the event an executive's employment is terminated by us other than for cause or as a result of the executive's death or permanent disability, or if the executive resigns for good reason, that portion of the executive's stock awards, and any unvested shares issued upon the exercise of such stock awards, which would have vested if the executive had remained employed for an additional 12 months following the date of termination will immediately vest on the date of termination. In addition, if an executive's employment is terminated by us other than for cause or if an executive resigns for good reason within three months prior to or twelve months following a change of control, all of the executive's remaining unvested stock awards, and any unvested shares issued upon the exercise of such stock awards, will immediately vest on the later of (1) the date of termination or (2) the date of the change of control. This accelerated vesting is in addition to any accelerated vesting provided under our stock option plans.

Provided that the relevant stock award agreements do not specify a longer exercise period, an executive may generally exercise his or her stock awards until three months after the date of the executive's termination of employment, except that the executive may also exercise his or her stock awards three months after the date of a change of control, if the executive's employment is terminated by us other than for cause or if the executive resigns for good reason within three months prior to a change of control, and if such stock awards were granted on or after the effective date of the executive's employment agreement. In no event, however, may an executive exercise any stock award later than its original outside expiration date.

In addition, the employment agreements provide that, in connection with a change of control, 50% of the executive's unvested stock awards, and any unvested shares issued upon the exercise of stock awards, will immediately become vested. This accelerated vesting is in addition to any accelerated vesting provided under our stock option plans.

The employment agreements also include standard noncompetition, nonsolicitation and nondisclosure covenants on the part of the executives. During the term of each executive's employment with us, the employment agreements provide that he or she may not compete with our business in any manner, except that an executive may own insignificant equity positions in publicly traded companies so long as the executive does not control such company. During the term of each executive's employment with us and for any period during which he or she is receiving severance, the employment agreements provide that he or she may not solicit our employees or consultants. The employment agreements also reaffirm the executives' obligations under our standard employee proprietary information and inventions agreement to which each executive is a party.

For purposes of the employment agreements, "cause" means, generally, the executive's commission of an act of fraud, embezzlement or dishonesty that has a material adverse impact on us, the executive's conviction of, or plea of guilty or no contest to a felony, the executive's unauthorized use or disclosure of our confidential information or trade secrets that has a material adverse impact on us, the executive's gross negligence, insubordination, material violation of any duty of loyalty to us or any other material misconduct on the part of the executive, the executive's ongoing and repeated failure or refusal to perform or neglect of his or her duties (where such failure, refusal or neglect continues for 15 days following the executive's receipt of written notice from our board), or a breach by the executive of any material provision of his or her employment agreement. Prior to any determination by us that "cause" has occurred, we will provide the executive with written notice of the reasons for such determination, afford the executive a reasonable opportunity to remedy any such breach, and provide the executive an opportunity to be heard prior to the final decision to terminate the executive's employment.

For purposes of the employment agreements, "good reason" means, generally, a change by us in the executive's position or responsibilities, other than a change in the executive's reporting relationship, that, in the executive's reasonable judgment, represents a substantial and material reduction in the position or responsibilities as in effect immediately prior thereto, our assignment to the executive of any duties or responsibilities that, in the executive's reasonable judgment, are materially inconsistent with such position or responsibilities, any removal of the executive from or failure to reappoint or reelect the executive to any of such positions, except in connection with the termination of the executive's employment for cause, as a result of his or her permanent disability or death, or by the executive other than for good reason, a material reduction in the executive's annual base salary (other than in connection with a general reduction in wages for personnel with similar status and responsibilities), our requiring the executive (without the executive's consent) to be based at any place outside a 50-mile radius of his or her initial place of employment with us, except for reasonably required travel on behalf of our business, our failure to provide the executive with compensation and benefits substantially equivalent (in terms of benefit levels and/or reward opportunities) to those provided for under each of our material employee benefit plans, programs and practices as in effect immediately prior to the date of the employment agreement, or any material breach by us of our obligations to the executive under the employment agreement.

Proprietary Information and Inventions Agreement

Each of our named executive officers has also entered into a standard form agreement with respect to proprietary information and inventions. Among other things, this agreement obligates each named executive officer to refrain from disclosing any of our proprietary information received during the course of employment and, with some exceptions, to assign to us any inventions conceived or developed during the course of employment.

Employee Benefit and Stock Plans

Annual Bonus Plan

In August 2006, our board of directors approved our 2006 corporate bonus plan. Pursuant to the 2006 corporate bonus plan, our board of directors designated for each executive officer a target bonus amount, expressed as a percentage of his or her base salary (40% for our chief executive officer, 30% for our executive vice presidents and senior vice presidents and 25% for our other executive officers). Our executive officers are eligible to receive bonuses if certain individual and corporate performance criteria are achieved during the 2006 fiscal year, and such bonuses are payable as cash, stock, options, or a combination of the foregoing. Bonus payments will be based on the compensation committee's evaluation of our achievement of corporate performance goals for 2006, which were determined by the compensation committee prior to the inception of the 2006 incentive plan. The use of corporate performance goals is intended to establish a link between the executive's pay and our business performance. The individual performance of each of the executive officers during 2006 will be evaluated according to the achievement of individual performance goals, which were approved by the president and chief executive officer and the relevant vice presidents prior to the inception of the 2006 incentive plan. Our president and chief executive officer will receive a bonus determined solely by reference to the achievement of corporate performance goals. The compensation committee is responsible for approving any bonuses to our executive officers pursuant to the 2006 incentive plan.

2006 Equity Incentive Award Plan

In August 2006, our board of directors approved our 2006 Equity Incentive Award Plan, or the 2006 plan, which was approved by our stockholders in August 2006. The 2006 plan will become effective on the day prior to the day of this offering.

We have initially reserved 2,100,000 shares of our common stock for issuance under the 2006 plan. In addition, the number of shares initially reserved under the 2006 plan will be increased by (i) the number of shares of common stock available for issuance and not subject to options granted under our 2004 equity incentive award plan as of the effective date of the 2006 plan, and (ii) the number of shares of common stock related to options granted under our 2004 equity incentive award plan that are repurchased, forfeited, expired or are cancelled on or after the effective date of the 2006 plan. The total number of shares described in clauses (i) and (ii) of the preceding sentence shall not exceed 2,875,000 shares of our common stock. The 2006 plan contains an "evergreen provision" that allows for an annual increase in the number of shares available for issuance under the 2006 plan on January 1 of each year during the ten-year term of the 2006 plan, beginning on January 1, 2008. The annual increase in the number of shares shall be equal to the lesser of:

- 4% of our outstanding common stock on the applicable January 1; and
- a lesser amount determined by our board of directors.

Notwithstanding the "evergreen provision", the 2006 plan also provides for an aggregate limit of 20,000,000 shares of common stock which may be issued under the 2006 plan over the course of its ten-year term. The material terms of the 2006 plan are summarized below. The 2006 plan is filed as an exhibit to the registration statement of which this prospectus is a part.

Administration. The compensation committee of our board of directors will administer the 2006 plan (except with respect to any award granted to "independent directors" (as defined in the 2006 plan), which must be administered by our full board of directors). To administer the 2006 plan, our compensation committee must consist of at least two members of our board of directors, each of whom is a "non-employee director" for purposes of Rule 16b-3 under the Securities Exchange Act of 1934, as amended, and, with respect to awards that are intended to constitute performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, as amended, an "outside director" for purposes of Section 162(m). Subject to the terms and conditions of the 2006 plan, our compensation committee has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, the number of awards to grant, the number of shares to be subject to such awards, and the terms and conditions of such awards, and to make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2006 plan. Our compensation committee is also authorized to adopt, amend or rescind rules relating to administration of the 2006 plan. Our board of directors may at any time abolish the compensation committee and revest in itself the authority to administer the 2006 plan. The full board of directors will administer the 2006 plan with respect to awards to non-employee directors.

Eligibility. Options, stock appreciation rights, or SARs, restricted stock and other awards under the 2006 plan may be granted to individuals who are then our officers or employees or are the officers or employees of any of our subsidiaries. Such awards may also be granted to our non-employee directors and consultants but only employees may be granted incentive stock options, or ISOs. The maximum number of shares that may be subject to awards granted under the 2006 plan to any individual in any calendar year cannot exceed 1,000,000.

Awards. The 2006 plan provides that our compensation committee (or the board of directors, in the case of awards to non-employee directors) may grant or issue stock options, SARs, restricted stock, restricted stock units, dividend equivalents, performance share awards, performance stock units, stock payments, deferred stock, performance bonus awards, performance-based awards, and other stock-based awards, or any combination thereof. The compensation committee (or the board of directors, in the case of awards to non-employee directors) will consider each award grant subjectively, considering factors such as the individual performance of the recipient and the anticipated contribution of the recipient to the attainment of the company's long-term goals. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

- Nonqualified stock options, or NQSOs, will provide for the right to purchase shares of our common stock at a specified price which may not be less than par value of a share of common stock on the date of grant, and usually will become exercisable (at the discretion of our compensation committee or the board of directors, in the case of awards to non-employee directors) in one or more installments after the grant date, subject to the participant's continued employment or service with us and/or subject to the satisfaction of performance targets established by our compensation committee (or the board of directors, in the case of awards to non-employee directors). NQSOs may be granted for any term specified by our compensation committee (or the board of directors, in the case of awards to non-employee directors), but the term may not exceed ten years.
- ISOs will be designed to comply with the provisions of the Internal Revenue Code and will be subject to specified restrictions contained in the Internal Revenue Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, must expire within a specified period of time following the optionee's termination of employment, and must be exercised within the ten years after the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of our capital stock, the 2006 plan provides that the exercise price must be more than 110% of the fair market value of a share of common stock on the date of grant and the ISO must expire upon the fifth anniversary of the date of its grant.

- Restricted stock may be granted to participants and made subject to such restrictions as may be determined by our compensation committee (or the board of directors, in the case of awards to non-employee directors). Typically, restricted stock may be forfeited for no consideration if the conditions or restrictions are not met, and they may not be sold or otherwise transferred to third parties until restrictions are removed or expire. Recipients of restricted stock, unlike recipients of options, may have voting rights and may receive dividends, if any, prior to the time when the restrictions lapse.
- Restricted stock units may be awarded to participants, typically without payment of consideration or for a nominal purchase price, but subject to vesting conditions including continued employment or on performance criteria established by our compensation committee (or the board of directors, in the case of awards to non-employee directors). Like restricted stock, restricted stock units may not be sold or otherwise transferred or hypothecated until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied.
- SARs may be granted in connection with stock options or other awards, or separately. SARs granted under the 2006 plan in connection with stock options or other awards typically will provide for payments to the holder based upon increases in the price of our common stock over the exercise price of the related option or other awards. Except as required by Section 162(m) of the Internal Revenue Code with respect to an SAR intended to qualify as performance-based compensation as described in Section 162(m) of the Internal Revenue Code, there are no restrictions specified in the 2006 plan on the exercise of SARs or the amount of gain realizable therefrom. Our compensation committee (or the board of directors, in the case of awards to non-employee directors) may elect to pay SARs in cash or in common stock or in a combination of both.
- Dividend equivalents represent the value of the dividends, if any, per share paid by us, calculated with reference to the number of shares covered by the stock options, SARs or other awards held by the participant.
- Performance awards (*i.e.*, performance share awards, performance stock units, performance bonus awards, performance-based awards and deferred stock) may be granted by our compensation committee (or the board of directors, in the case of awards to non-employee directors) on an individual or group basis. Generally, these awards will be based upon specific performance targets and may be paid in cash or in common stock or in a combination of both. Performance awards may include “phantom” stock awards that provide for payments based upon increases in the price of our common stock over a predetermined period. Performance awards may also include bonuses that may be granted by our compensation committee (or the board of directors, in the case of awards to non- employee directors) on an individual or group basis, which may be paid on a current or deferred basis and may be payable in cash or in common stock or in a combination of both. The maximum amount of any such bonuses to a “covered employee” within the meaning of Section 162(m) of the Code shall not exceed $1,000,000 for any fiscal year during the term of the 2006 plan.
- Stock payments may be authorized by our compensation committee (or the board of directors, in the case of awards to non-employee directors) in the form of common stock or an option or other right to purchase common stock as part of a deferred compensation arrangement, made in lieu of all or any part of compensation, including bonuses, that would otherwise be payable to employees or consultants or members of our board of directors.

Corporate Transactions. In the event of a change of control where the acquiror does not assume awards granted under the plan, awards issued under the 2006 plan will be subject to accelerated vesting

such that 100% of the awards will become vested and exercisable or payable, as applicable. Under the 2006 plan, a change of control is generally defined as:

- the direct or indirect sale or exchange in a single or series of related transactions (other than an offering of our stock to the general public through a registration statement filed with the SEC) whereby any person or entity or related group of persons or entities (other than us, our subsidiaries, an employee benefit plan maintained by us or any of our subsidiaries or a person or entity that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, us) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of more than 50% of the total combined voting power of our securities outstanding immediately after such acquisition;
- during any two-year period, individuals who, at the beginning of such period, constitute our board of directors together with any new director(s) whose election by our board of directors or nomination for election by our stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority of our board of directors;
- the merger, consolidation, reorganization, or business combination in which the company is a party (whether directly involving the company or indirectly involving the company through one or more intermediaries, other than a merger, consolidation, reorganization, or business combination that results in our outstanding voting securities immediately before the transaction continuing to represent a majority of the voting power of the acquiring company's outstanding voting securities or a merger, consolidation, reorganization, or business combination after which no person or entity owns 50% of the successor company's voting power); and
- the sale, exchange or transfer of all or substantially all of our assets.

Amendment and Termination of the 2006 Plan. Our board of directors may terminate, amend or modify the 2006 plan. However, stockholder approval of any amendment to the 2006 plan will be obtained to the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule, or for any amendment to the 2006 plan that increases the number of shares available under the 2006 plan. If not terminated earlier by the compensation committee or the board of directors, the 2006 plan will terminate on the tenth anniversary of the date of its initial approval by our board of directors.

Securities Laws and Federal Income Taxes. The 2006 plan is designed to comply with various securities and federal tax laws as follows:

- *Securities Laws.* The 2006 plan is intended to conform to all provisions of the Securities Act and the Exchange Act and any and all regulations and rules promulgated by the SEC thereunder, including without limitation, Rule 16b-3. The 2006 plan will be administered, and awards will be granted and may be exercised, only in such a manner as to conform to such laws, rules and regulations.
- *General Federal Tax Consequences.* Under current federal laws, in general, recipients of awards and grants of NQSOs, SARs, restricted stock, restricted stock units, dividend equivalents, performance awards and stock payments under the plan are taxable under Section 83 of the Internal Revenue Code upon their receipt of common stock or cash with respect to such awards or grants and, subject to Section 162(m) of the Internal Revenue Code, we will be entitled to an income tax deduction with respect to the amounts taxable to such recipients. However, Section 409A of the Internal Revenue Code provides certain new requirements on non-qualified deferred compensation arrangements. Certain awards under the 2006 plan are subject to the requirements of Section 409A, in form and in operation, such as restricted stock unit awards. We intend that all plan awards that are subject to Section 409A will satisfy the requirements of Section 409A. However, if a plan award is

subject to and fails to satisfy the requirements of Section 409A, the recipient of that award may recognize ordinary income on the amounts deferred under the award, to the extent vested, which may be prior to when the compensation is actually or constructively received. Also, if an award that is subject to Section 409A fails to comply, Section 409A imposes an additional 20% federal income tax on compensation recognized as ordinary income, as well as interest on such deferred compensation.

Under Sections 421 and 422 of the Internal Revenue Code, recipients of ISOs are generally not taxed on their receipt of common stock upon their exercises of ISOs if the ISOs and option stock are held for specified minimum holding periods and, in such event, we are not entitled to income tax deductions with respect to such exercises. Participants in the 2006 plan will be provided with detailed information regarding the tax consequences relating to the various types of awards and grants under the 2006 plan.

- *Section 162(m) Limitation.* In general, under Section 162(m) of the Internal Revenue Code, income tax deductions of publicly-held corporations may be limited to the extent total compensation (including base salary, annual bonus, stock option exercises and non-qualified benefits paid) for certain executive officers exceeds $1 million (less the amount of any "excess parachute payments" as defined in Section 280G of the Internal Revenue Code) in any one year. However, under Section 162(m), the deduction limit does not apply to certain "performance-based compensation" if an independent compensation committee determines performance goals, and if the material terms of the performance-based compensation are disclosed to and approved by our stockholders. In particular, stock options and SARs will satisfy the "performance-based compensation" exception if the awards are made by a qualifying compensation committee, the 2006 plan sets the maximum number of shares that can be granted to any person within a specified period and the compensation is based solely on an increase in the stock price after the grant date. Specifically, the option exercise price must be equal to or greater than the fair market value of the stock subject to the award on the grant date. Under a Section 162(m) transition rule for compensation plans of corporations which are privately held and which become publicly held in an initial public offering, the 2006 plan will not be subject to Section 162(m) until a specified transition date, which is the earlier of (i) the material modification of the 2006 plan, (ii) the issuance of all employer stock and other compensation that has been allocated under the 2006 plan, or (iii) the first annual meeting of stockholders at which directors are to be elected that occurs after the close of the third calendar year following the calendar year in which the initial public offering occurs. After the transition date, rights or awards granted under the 2006 plan, other than options and SARs, will not qualify as "performance-based compensation" for purposes of Section 162(m) unless such rights or awards are granted or vest upon pre-established objective performance goals, the material terms of which are disclosed to and approved by our stockholders.

We have attempted to structure the 2006 plan in such a manner that, after the transition date, the compensation attributable to stock options and SARs which meet the other requirements of Section 162(m) will not be subject to the $1 million limitation. We have not, however, requested a ruling from the Internal Revenue Service, or IRS, or an opinion of counsel regarding this issue.

2004 Equity Incentive Award Plan

Our 2004 equity incentive award plan, or 2004 plan, was initially adopted by our board of directors and approved by our stockholders in November 2004. As amended to date, we have reserved a total of 2,875,000 shares of common stock for issuance under the 2004 plan. As of June 30, 2006, options to purchase 1,020,435 shares of common stock had been exercised (7,500 shares of which were repurchased by us), options to purchase 1,442,372 shares of common stock were outstanding and 419,693 shares of common stock remained available for grant. As of June 30, 2006, the outstanding options were exercisable at a weighted average exercise price of approximately $1.52 per share. The material terms of the 2004 plan

are summarized below. The 2004 plan is filed as an exhibit to the registration statement of which this prospectus is a part.

No Further Grants. After the effective date of the 2006 Plan, no additional awards will be granted under the 2004 plan.

Administration. The compensation committee of our board of directors administers the 2004 plan. Following the completion of this offering, to administer the 2004 plan, our compensation committee must be constituted as described above in our description of the 2006 Plan. Subject to the terms and conditions of the 2004 plan, our compensation committee has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject thereto and the terms and conditions thereof, and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2004 plan. Our compensation committee is also authorized to establish, adopt, amend or rescind rules relating to administration of the 2004 plan. Our board of directors may at any time abolish the compensation committee and revest in itself the authority to administer the 2004 plan. The full board of directors administers the 2004 plan with respect to awards to non-employee directors.

Eligibility. Options and restricted stock under the 2004 plan may be granted to individuals who are then our officers or employees or are the officers or employees of any of our subsidiaries. Such awards may also be granted to our non-employee directors or consultants, but only employees may be granted ISOs.

Awards. The 2004 plan provides that our compensation committee may grant or issue stock options and restricted stock, stock appreciation rights, performance share awards, restricted stock units, dividend equivalents, stock payments or performance-based awards or any combination thereof. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

- NQSOs provide for the right to purchase shares of our common stock at a specified price, which for purposes of the 2004 plan prior to the date of this offering, may be no less than 85% of the fair market value on the date of grant, and usually will become exercisable (at the discretion of our compensation committee (or the board of directors, in the case of awards to non-employee directors), in one or more installments after the grant date, subject to the participant's continued employment or service with us and/or subject to the satisfaction of performance targets established by our compensation committee (or the board of directors, in the case of awards to non-employee directors). NQSOs may be granted for a maximum 10-year term.
- ISOs are designed to comply with the provisions of the Internal Revenue Code and will be subject to specified restrictions contained in the Internal Revenue Code and as further described above in connection with the 2006 Equity Incentive Award Plan.

To date, we have only granted stock options under the 2004 plan.

Corporate Transactions. In the event of a change of control where the acquiror does not assume awards granted under the plan and does not substitute substantially similar awards for those outstanding under the plan, awards issued under the plan will be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable. Under the 2004 plan, a change of control is generally defined as:

- a merger or consolidation of us with or into any other corporation or other entity or person; or
- a sale, lease, exchange or other transfer in one transaction or a series of related transactions of all or substantially all of our outstanding securities or all or substantially all of our assets.

Amendment and Termination of the 2004 plan. The compensation committee, with the approval of the board of directors, may terminate, amend or modify the 2004 plan. However, stockholder approval of any amendment to the 2004 plan will be obtained to the extent necessary and desirable to comply with

any applicable law, regulation, or stock exchange rule. If not terminated earlier by the compensation committee, with the approval of the board of directors, the 2004 plan will terminate on the tenth anniversary of the date of its initial adoption by our board of directors.

401(k) Plan

We provide a basic savings plan, or 401(k) plan, which is intended to qualify under Section 401(k) of the Internal Revenue Code so that contributions to our 401(k) plan by employees or by us, and the investment earnings thereon, are not taxable to employees until withdrawn from our 401(k) plan. If our 401(k) plan qualifies under Section 401(k) of the Internal Revenue Code, contributions by us, if any, will be deductible by us when made.

All of our employees are eligible to participate in our 401(k) plan. Pursuant to our 401(k) plan, employees may elect to reduce their current compensation by up to the statutorily-prescribed annual limit of $15,000 in 2006 and to have the amount of this reduction contributed to our 401(k) plan. Our 401(k) plan permits, but does not require, additional matching or non-elective contributions to our 401(k) plan by us on behalf of all participants in our 401(k) plan. To date, we have not made any matching or non-elective contributions to our 401(k) plan.

Limitations of Liability and Indemnification Matters

We will adopt provisions in our amended and restated certificate of incorporation that limit the liability of our directors for monetary damages for breach of their fiduciary duties, except for liability that cannot be eliminated under the Delaware General Corporation Law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following:

- any breach of their duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also will provide that we shall indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. We believe that indemnification under our amended and restated bylaws covers at least negligence and gross negligence on the part of indemnified parties. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our charter documents. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person’s services as a director or executive officer or at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers.

PRINCIPAL STOCKHOLDERS

The following table sets forth information about the beneficial ownership of our common stock at September 30, 2006, and as adjusted to reflect the sale of the shares of common stock in this offering, for:

- each person known to us to be the beneficial owner of more than 5% of our common stock;
- each named executive officer and two additional executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Unless otherwise noted below, the address of each beneficial owner listed on the table is c/o Cadence Pharmaceuticals, Inc., 12481 High Bluff Drive, Suite 200, San Diego, CA 92130. We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, we believe, based on the information furnished to us by the stockholders, that the persons and entities named in the tables below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws. We have based our calculation of the percentage of beneficial ownership on 22,085,540 shares of common stock outstanding on September 30, 2006, which assumes the conversion of all outstanding shares of preferred stock into common stock and 28,085,540 shares of common stock outstanding upon completion of this offering.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of September 30, 2006. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned	
		Prior to Offering	After Offering
5% or Greater Stockholders:			
Funds affiliated with Domain Associates, L.L.C.(1) One Palmer Square, Suite 515 Princeton, NJ 08542	5,741,122	26.0%	20.4%
ProQuest Investments III, L.P.(2) 90 Nassau Street, 5th Floor Princeton, NJ 08542	3,080,674	13.9	11.0
Frazier Healthcare V, LP(3) 601 Union Street, Suite 3200 Seattle, WA 98101	2,525,000	11.4	9.0
Funds affiliated with Versant Ventures II, L.L.C.(4) 3000 Sand Hill Road Building 4, Suite 210 Menlo Park, CA 94025	2,024,998	9.2	7.2
Funds affiliated with Technology Partners(5) 100 Shoreline Highway Suite 282, Building B Mill Valley, CA 94941	2,000,000	9.1	7.1
BB Biotech Ventures II, L.P.(6) Trafalgar Court, Les Banques St Peter Port, Guernsey, Channel Islands GY1 3QL	1,750,000	7.9	6.2

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned	
		Prior to Offering	After Offering
Directors and Executive Officers:			
Theodore R. Schroeder(7)	1,010,936	4.5	3.5
James B. Breitmeyer, M.D., Ph.D.(8)	176,250	*	*
William S. Craig, Ph.D.(9)	176,327	*	*
Kenneth R. Heilbrunn, M.D.(10)	79,428	*	*
William R. LaRue(11)	224,750	1.0	*
Richard E. Lowenthal(12)	141,000	*	*
Mike A. Royal, M.D., J.D.(13)	93,750	*	*
David A. Socks(14)	423,183	1.9	1.5
Cam L. Garner(15)	1,062,530	4.8	3.8
Brian G. Atwood(4)	2,024,998	9.2	7.2
Samuel L. Barker, Ph.D.(16)	25,000	*	*
Michael A. Berman, M.D.(17)	25,000	*	*
James C. Blair, Ph.D.(1)	5,741,122	26.0	20.4
Alan D. Frazier(3)	2,525,000	11.4	9.0
Alain B. Schreiber, M.D.(2)	3,080,674	13.9	11.0
Christopher J. Twomey(18)	25,000	*	*
Executive officers and directors as a group (16 persons)(19)	16,834,948	71.1	56.8

* Represents beneficial ownership of less than one percent of our outstanding common stock.

(1) Includes 5,653,038 shares of common stock owned by Domain Partners VI, L.P., 60,584 shares of common stock owned by DP VI Associates, L.P. and 27,500 shares of common stock owned by Domain Associates, L.L.C. Of the 27,500 shares owned by Domain Associates, 20,625 will be subject to our right of repurchase within 60 days of September 30, 2006. Dr. Blair is a member of our board of directors and a managing member of Domain Associates, L.L.C. and a managing member of One Palmer Square Associates VI, L.L.C., which is the general partner of Domain Partners VI, L.P. and DP VI Associates, L.P. Dr. Blair disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(2) Includes 3,053,174 shares of common stock owned by ProQuest Investments III, L.P. and 12,500 shares of common stock owned by ProQuest Management LLC. Of the 12,500 shares owned by ProQuest Management, 4,375 will be subject to our right of repurchase within 60 days of September 30, 2006. Also includes 15,000 shares Dr. Schreiber has the right to acquire pursuant to outstanding options which are immediately exercisable, 13,750 of which would be subject to our right of repurchase within 60 days of September 30, 2006. Dr. Schreiber is a member of our board of directors and a managing member of ProQuest Management LLC and a managing member of ProQuest Associates III LLC, the ultimate general partner of ProQuest Investments III, L.P.

(3) Includes 25,000 shares Mr. Frazier has the right to acquire pursuant to outstanding options which are immediately exercisable, 21,875 of which would be subject to our right of repurchase within 60 days of September 30, 2006. The voting and disposition of the shares held by Frazier Healthcare V, LP is determined by FHM V, LLC, which is the general partner of FHM V, LP, which is the general partner of Frazier Healthcare V, LP. Mr. Frazier is a member of our board of directors and a managing member of FHM V, LLC. Mr. Frazier disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

footnotes continued on the following page

(4) Includes 1,945,686 shares of common stock owned by Versant Venture Capital II, L.P., 36,923 shares of common stock owned by Versant Affiliates Fund II-A, L.P. and 17,389 shares of common stock owned by Versant Side Fund II, L.P. Also includes 25,000 shares Mr. Atwood has the right to acquire pursuant to outstanding options which are immediately exercisable, 21,875 of which would be subject to our right of repurchase within 60 days of September 30, 2006. Mr. Atwood is a member of our board of directors and a managing member of Versant Ventures II, L.L.C., which is the general partner of each of these Versant funds. Mr. Atwood disclaims beneficial ownership of shares owned by these Versant funds except to the extent of his pecuniary interest therein.

(5) Includes 1,880,000 shares of common stock owned by Technology Partners Fund VII, L.P. and 120,000 shares of common stock owned by Technology Partners Affiliates VII, L.P. The voting and disposition of the shares held by Technology Partners Fund VII, L.P. and Technology Partners Affiliates VII is determined by TP Management VII, L.L.C., which is the general partner of each of these Technology Partners funds. John E. Ardell III, Ira Ehrenpreis, James Glasheen, Sheila Mutter and Roger J. Quy share voting and dispositive authority over the shares held by Technology Partners.

(6) The voting and disposition of the shares held by BB Biotech Ventures II, L.P. is determined by its general partner, BB Biotech Ventures GP (Guernsey) Limited. Christopher Wilfred Cochrane, Benedict Peter Goronwy Morgan and Hans Jorg Graf, in their capacities as directors of the general partner, share voting and dispositive authority over the shares held by BB Biotech Ventures.

(7) Includes 510,936 shares Mr. Schroeder has the right to acquire pursuant to outstanding options which are immediately exercisable, all of which would be subject to our right of repurchase within 60 days of September 30, 2006. Also includes 250,000 unvested shares acquired by Mr. Schroeder upon the early exercise of stock options, 148,438 of which will be subject to our right of repurchase within 60 days of September 30, 2006. Also includes 250,000 shares acquired by Mr. Schroeder as one of our co-founders.

(8) Includes 176,250 shares Dr. Breitmeyer has the right to acquire pursuant to outstanding options that are immediately exercisable, all of which would be subject to our right of repurchase within 60 days of September 30, 2006.

(9) Includes 176,327 shares Dr. Craig has the right to acquire pursuant to outstanding options which are immediately exercisable, 132,577 of which would be subject to our right of repurchase within 60 days of September 30, 2006.

(10) Includes 79,428 shares Dr. Heilbrunn has the right to acquire pursuant to outstanding options that are immediately exercisable, none of which would be subject to our right of repurchase within 60 days of September 30, 2006. Effective September 30, 2006, Dr. Heilbrunn resigned as our Senior Vice President, Clinical Development.

(11) Includes 11,000 shares acquired by Mr. LaRue upon exercise of stock options, 7,563 of which will be subject to our right of repurchase within 60 days of September 30, 2006. These 11,000 shares are held by a trust for the benefit of Mr. LaRue's family. Also includes 213,750 shares of common stock Mr. LaRue has the right to acquire pursuant to outstanding options that are immediately exercisable, all of which would be subject to our right of repurchase within 60 days of September 30, 2006.

(12) Includes 141,000 shares acquired by Mr. Lowenthal upon the exercise of stock options, 105,063 of which will be subject to our right of repurchase within 60 days of September 30, 2006. These 141,000 shares are held of record by a trust for the benefit of Mr. Lowenthal's family.

(13) Includes 93,750 shares Dr. Royal has the right to acquire pursuant to outstanding options which are immediately exercisable, all of which would be subject to our right of repurchase within 60 days of September 30, 2006.

footnotes continued on the following page

(14) Includes 210,683 shares Mr. Socks has the right to acquire pursuant to outstanding options which are immediately exercisable, 197,142 of which would be subject to our right of repurchase within 60 days of September 30, 2006. Also includes 212,500 shares acquired by Mr. Socks as one of our co-founders.

(15) Includes 573,435 shares acquired by Mr. Garner upon the exercise of stock options, 514,604 of which will be subject to our right of repurchase within 60 days of September 30, 2006. Of these 573,435 shares, 538,435 shares are held of record by a trust for which Mr. Garner serves as trustee and 35,000 shares are held by a limited liability company for which Mr. Garner is the sole member. Also includes 437,500 shares acquired by Mr. Garner as one of our co-founders. Of these 437,500 shares, 400,000 shares are held by a limited liability company for which Mr. Garner is the sole member and 37,500 shares are held by siblings of Mr. Garner. Also includes 51,595 shares acquired by a limited liability company for which Mr. Garner is the sole member.

(16) Includes 25,000 shares Dr. Barker has the right to acquire pursuant to outstanding options which are immediately exercisable, 22,917 of which would be subject to our right of repurchase within 60 days of September 30, 2006.

(17) Includes 25,000 shares Dr. Berman has the right to acquire pursuant to outstanding options which are immediately exercisable, 22,500 of which would be subject to our right of repurchase within 60 days of September 30, 2006.

(18) Includes 25,000 shares acquired by Mr. Twomey upon exercise of stock options, 22,917 of which would be subject to our right of repurchase within 60 days of September 30, 2006. These 25,000 shares are held of record by a trust for the benefit of Mr. Twomey's family.

(19) Includes 1,576,124 shares of common stock subject to outstanding options which are immediately exercisable, 1,427,322 of which would be subject to our right of repurchase within 60 days of September 30, 2006. Includes 1,040,435 shares of common stock acquired upon the exercise of options, 823,585 of which will be subject to our right of repurchase within 60 days of September 30, 2006.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

We describe below transactions and series of similar transactions, since our inception, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $60,000; and
- a director, executive officer, holder of more than 5% of our common stock or any member of their immediate family had or will have a direct or indirect material interest.

We also describe below certain other transactions with our directors, executive officers and stockholders.

Preferred Stock Issuances

In July and August 2004, we issued in a private placement an aggregate of 8,085,108 shares of Series A-1 preferred stock at a per share price of $0.94, for aggregate consideration of $7,600,002. In June and September 2005, we issued in a private placement an aggregate of 17,675,347 shares of Series A-2 preferred stock at a per share price of $1.00, for aggregate consideration of $17,675,347. In March 2006, we issued in a private placement 53,870,000 shares of Series A-3 preferred stock at a per share price of $1.00, for aggregate consideration of $53,870,000.

The following table sets forth the aggregate number of these securities acquired by the listed directors, executive officers or holders of more than 5% of our common stock, or their affiliates:

	Shares of Preferred Stock		
Investor	**Series A-1**	**Series A-2**	**Series A-3**
Funds affiliated with Domain Associates, L.L.C.(1)	3,989,362	6,365,130	12,500,000
ProQuest Investments III, L.P.(2)	2,393,618	3,819,080	6,000,000
Frazier Healthcare V, LP(3)	—	—	10,000,000
Funds affiliated with Versant Ventures II, L.L.C.(4)	—	—	8,000,000
Funds affiliated with Technology Partners(5)	—	—	8,000,000
BB Biotech Ventures II, L.P.(6)	—	3,000,000	4,000,000
Cam L. Garner(7)	106,383	—	100,000

(1) Includes 3,947,061 shares of Series A-1 preferred stock, 6,297,638 shares of Series A-2 preferred stock and 12,367,456 shares of Series A-3 preferred stock owned by Domain Partners VI, L.P., and 42,301 shares of Series A-1 preferred stock, 67,492 shares of Series A-2 preferred stock, and 132,544 shares of Series A-3 preferred stock owned by DP VI Associates, L.P. Dr. Blair, a member of our board of directors, is a managing member of Domain Associates, L.L.C. and a managing member of One Palmer Square Associates VI, L.L.C., which is the general partner of Domain Partners VI, L.P. and DP VI Associates, L.P.

(2) The voting and disposition of the shares held by ProQuest Investments III, L.P. is determined by ProQuest Associates III LLC, the ultimate general partner of ProQuest Investments III, L.P. Dr. Schreiber, a member of our board of directors, is a managing member of ProQuest Associates III LLC.

(3) The voting and disposition of the shares held by Frazier Healthcare V, LP is determined by FHM V, LLC, which is the general partner of FHM V, LP, which is the general partner of Frazier Healthcare V, LP. Mr. Frazier, a member of our board of directors, is a managing member of FHM V, LLC.

footnotes continued on the following page

(4) Includes 7,782,747 shares of Series A-3 preferred stock owned by Versant Venture Capital II, L.P., 147,695 shares of Series A-3 preferred stock owned by Versant Affiliates Fund II-A, L.P., and 69,558 shares of Series A-3 preferred stock owned by Versant Side Fund II, L.P. Mr. Atwood, a member of our board of directors, is a managing member of Versant Ventures II, L.L.C., which is the general partner of each of these Versant funds.

(5) Includes 7,520,000 shares of Series A-3 preferred stock owned by Technology Partners Fund VII, L.P. and 480,000 shares of Series A-3 preferred stock owned by Technology Partners Affiliates VII, L.P. The voting and disposition of the shares held by Technology Partners Fund VII, L.P. and Technology Partners Affiliates VII is determined by TP Management VII, L.L.C., which is the general partner of each of these Technology Partners funds. John E. Ardell III, Ira Ehrenpreis, James Glasheen, Sheila Mutter and Roger J. Quy share voting and dispositive authority over the shares held by Technology Partners.

(6) The voting and disposition of the shares held by BB Biotech Ventures II, L.P. is determined by its general partner, BB Biotech Ventures GP (Guernsey) Limited. Christopher Wilfred Cochrane, Benedict Peter Goronwy Morgan and Hans Jorg Graf, in their capacities as directors of the general partner, share voting and dispositive authority over the shares held by BB Biotech Ventures.

(7) Shares held by a limited liability company for which Mr. Garner is the sole member.

Common Stock Issuances

In July 2004, in connection with the inception of our company, we issued and sold a total of 1,125,000 shares of common stock for an aggregate consideration of $4,500. The price for the common stock was determined through negotiations between our board of directors and the purchasers based primarily on the early stage of our development at the time of the transaction. The following table sets forth the aggregate number of these securities acquired by the listed directors and executive officers or their affiliates:

Investor	Common Stock
Cam L. Garner(1)	437,500
Theodore R. Schroeder(2)	250,000
David A. Socks	212,500

(1) Of these 437,500 shares, 400,000 shares are held by a limited liability company for which Mr. Garner is the sole member and 37,500 shares are held by siblings of Mr. Garner.

(2) Shares held by a trust for the benefit of Mr. Schroeder’s family.

Investor Rights Agreement

We have entered into an agreement with purchasers of our preferred stock that provides for certain rights relating to the registration of their shares of common stock issuable upon conversion of their preferred stock. The agreement also provides these rights to shares of common stock held by Messrs. Schroeder and Socks. These rights will continue following this offering and will terminate seven years following the completion of this offering, or for any particular holder with registration rights, at such time following this offering when all securities held by that stockholder subject to registration rights may be sold pursuant to Rule 144 under the Securities Act. All holders of our preferred stock are parties to this agreement. See “Description of Capital Stock — Registration Rights” for additional information.

Voting Agreement

Pursuant to a voting agreement originally entered into in July 2004 and most recently amended in March 2006 by and among us and certain of our stockholders, the following directors were each elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Drs. Barker, Berman, Blair and Schreiber and Messrs. Atwood, Frazier, Garner and Schroeder. Pursuant to the voting agreement, Mr. Schroeder, as our president and chief executive officer, and Mr. Garner were initially selected to serve on our board of directors as representatives of our common stock, as designated by a majority of our common stockholders. Dr. Schreiber and Messrs. Atwood, Blair and Frazier were initially selected to serve on our board of directors as representatives of our preferred stock, as designated by ProQuest Investments III, L.P., Versant Venture Capital II, L.P., Domain Partners VI, L.P. and Frazier Healthcare V, LP, respectively. Drs. Barker and Berman and Mr. Twomey were selected to serve on our board of directors as representatives of our common stock and preferred stock, as designated by a majority of our common and preferred stockholders.

The voting agreement will terminate upon completion of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until their successors are duly elected by holders of our common stock.

Stock Option Grants

Certain stock option grants to our directors and executive officers and related option grant policies are described in this prospectus under the captions "Management — Director Compensation" and "Management — Option Grants in Last Fiscal Year." Prior to this offering, we granted the following options to certain non-employee directors:

- In November 2004, we granted to Dr. Schreiber an option to purchase 10,000 shares of our common stock at an exercise price of $0.40 per share, vesting over 16 calendar quarters from September 2004.
- In November 2005, we granted to Dr. Blair an option to purchase 10,000 shares of our common stock at an exercise price of $0.40 per share, vesting over 16 calendar quarters from September 2005.
- In November 2005, we granted to each of Dr. Schreiber and Mr. Garner an option to purchase 2,500 shares of our common stock at an exercise price of $0.40 per share, vesting over four calendar quarters from September 2005.
- In December 2005, we granted to Mr. Garner an option to purchase 340,500 shares of our common stock at an exercise price of $0.40 per share, vesting over four years from December 2005.
- In May 2006, we granted to Mr. Garner an option to purchase 195,435 shares of our common stock at an exercise price of $1.36 per share, vesting over four years from February 2006.
- In May 2006, we granted to Dr. Berman an option to purchase 10,000 shares of our common stock at an exercise price of $1.36 per share, vesting over 16 calendar quarters from April 2006.
- In May 2006, we granted to each of Messrs. Atwood and Frazier an option to purchase 10,000 shares of our common stock at an exercise price of $1.36 per share, vesting over 16 calendar quarters from March 2006.
- In July 2006, we granted to Mr. Twomey an option to purchase 25,000 shares of our common stock at an exercise price of $3.20 per share, vesting over 12 calendar quarters from July 2006.

- In July 2006, we granted to each of Mr. Atwood, Drs. Berman and Blair, Mr. Frazier and Dr. Schreiber an option to purchase 15,000 shares of our common stock at an exercise price of $3.20 per share, vesting over 12 calendar quarters from July 2006.
- In August 2006, we granted to Dr. Barker an option to purchase 25,000 shares of our common stock at an exercise price of $3.20 per share, vesting over 12 calendar quarters from August 2006.

In addition, we granted to each of Messrs. Craig and Socks an option in May 2006 to purchase 88,827 and 185,683, respectively, shares of our common stock at an exercise price of $1.36 per share. In June 2006, we granted to each of Mr. LaRue and Dr. Royal an option to purchase 176,250 and 75,000, respectively, shares of our common stock at an exercise price of $3.20 per share. In August 2006, we granted to Dr. Breitmeyer an option to purchase 176,250 shares of our common stock at an exercise price of $3.20 per share. Also in August 2006, we granted to each of Mr. LaRue and Dr. Royal an option to purchase 37,500 and 18,750 shares of our common stock at an exercise price of $3.20 per share. Each of these options vests with respect to 25% of the shares subject to the option one year after the applicable vesting commencement date and monthly thereafter over the following three years.

Employment Agreements

We have entered into employment agreements with Theodore R. Schroeder, our President and Chief Executive Officer, James B. Breitmeyer, M.D., Ph.D., our Executive Vice President, Development and Chief Medical Officer, William S. Craig, Ph.D., our Senior Vice President, Pharmaceutical Development and Manufacturing, William R. LaRue, our Senior Vice President, Chief Financial Officer, Treasurer and Secretary, Richard E. Lowenthal, our Vice President, Regulatory Affairs and Quality Assurance, Mike A. Royal, M.D., J.D. our Vice President, Clinical Development, Analgesics, and David A. Socks, our Vice President, Business Development. For further information, see “Management — Employment Agreements.”

Indemnification of Officers and Directors

Our restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have entered into indemnification agreements with each of our directors and officers, and we have purchased a policy of directors’ and officers’ liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see “Management — Limitations of Liability and Indemnification Matters.”

Consulting Agreement with Mr. Cam L. Garner

From September 2004 through August 2005, we paid Mr. Garner $5,000 per month plus qualified business expenses for his services as chairman of our board of directors under the terms of a consulting agreement between us and a limited liability company affiliated with Mr. Garner. The agreement expired on August 31, 2005.

Other Transactions

During 2004, Windamere III, LLC, a limited liability company affiliated with our former director, Scott L. Glenn, advanced $500,000 for pre-operating expenses and an exclusivity fee due in connection with the Collaboration and License Agreement between us and Migenix. The advance was settled with 531,915 shares of our Series A-1 preferred stock.

In September 2006, Kenneth R. Heilbrunn, M.D., our former Senior Vice President, Clinical Development, resigned. In accordance with the terms of his employment agreement, we are 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 allows for the acceleration of vesting for those options that would vest one year from the date of termination.

DESCRIPTION OF CAPITAL STOCK

Upon completion of this offering and filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of 100,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share. The following description summarizes some of the terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our amended and restated certificate of incorporation and amended and restated bylaws, copies of which have been filed as exhibits to the registration statement of which the prospectus is a part.

Common Stock

On June 30, 2006, there were 2,137,935 shares of common stock outstanding, held of record by 15 stockholders. This amount excludes our outstanding shares of preferred stock as of June 30, 2006 which will convert into 19,907,605 shares of common stock upon completion of the offering. After this offering, there will be 28,045,540 shares of our common stock outstanding, or 28,945,540 shares if the underwriters exercise their overallotment option in full.

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. Upon our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities of our company, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock to be outstanding upon completion of this offering will be, fully paid and nonassessable.

Preferred Stock

On June 30, 2006, there were 79,630,455 shares of preferred stock outstanding, held of record by 32 stockholders. Our stockholders have agreed to convert their shares of preferred stock to common stock in connection with the completion of this offering. Accordingly, upon the completion of this offering, all outstanding shares of preferred stock as of June 30, 2006 will automatically convert into 19,907,605 shares of our common stock.

Following the offering, our board of directors will have the authority, without any action by the stockholders, to issue from time to time preferred stock in one or more series and to fix the number of shares, designations, preferences, powers, and relative, participating, optional or other special rights and the qualifications or restrictions thereof. The preferences, powers, rights and restrictions of different series of preferred stock may differ with respect to dividend rates, amounts payable on liquidation, voting rights, conversion rights, redemption provisions, sinking fund provisions, and purchase funds and other matters. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to holders of common stock or adversely affect the rights and powers, including voting rights, of the holders of common stock, and may have the effect of delaying, deferring or preventing a change in control of our company. The existence of authorized but unissued preferred stock may enable the board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, the board of directors were to determine that a takeover proposal is not in our best interests, the board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more

private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group.

Warrants

In February 2006, in connection with our loan and security agreement, we issued a warrant to purchase up to an aggregate of 192,500 shares of our Series A-2 preferred stock to each of Silicon Valley Bank and Oxford Finance Corporation. These warrants are immediately exercisable at an exercise price of $1.00 per share and, excluding certain mergers or acquisitions, expire upon the later of ten years from the date of grant, which is February 17, 2016, or five years after the closing of this offering. These warrants will become exercisable for an aggregate of 96,250 shares of our common stock, at an exercise price of $4.00 per share, upon completion of this offering.

Each of these warrants has a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive, after this offering, a net amount of shares of our common stock based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants for common stock also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of stock dividends, stock splits, reorganizations and reclassifications and consolidations.

Registration Rights

After this offering, the holders of approximately 21,330,113 shares of common stock and the holders of warrants to purchase 96,250 shares of common stock will be entitled to rights with respect to the registration of these shares under the Securities Act. These shares are referred to as registrable securities. Under the terms of the agreement between us and the holders of the registrable securities, if we propose to register any of our securities under the Securities Act, these holders are entitled to notice of such registration and are entitled to include their shares of registrable securities in our registration. Certain of these holders are also entitled to demand registration, pursuant to which they may require us to use our best efforts to register their registrable securities under the Securities Act at our expense, up to a maximum of two such registrations. Holders of registrable securities may also require us to file an unlimited number of additional registration statements on Form S-3 at our expense so long as the holders propose to sell registrable securities of at least $1.0 million and we have not already filed two such registration statements on Form S-3 in the previous twelve months.

All of these registration rights are subject to certain conditions and limitations, among them the right of the underwriters of an offering to limit the number of shares included in such registration and our right not to effect a requested registration 60 days prior to or 180 days after an offering of our securities, including this offering. These registration rights have been waived by all of the holders thereof with respect to this offering.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Amended and Restated Bylaws and Delaware Law

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased

protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our charter documents provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Election and Removal of Directors

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see “Management — Board of Directors.” This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least 66²/₃% of our then outstanding common stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile

takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, located at 59 Maiden Lane, Plaza Level, New York, NY 10038.

Nasdaq Global Market Listing

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol “CADX.”

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Sales of Restricted Shares

Upon the closing of this offering, we will have outstanding an aggregate of approximately 28,045,540 shares of common stock, based on 22,045,540 shares outstanding as of June 30, 2006. Of these shares, the 6,000,000 shares of common stock to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act. All remaining shares of common stock held by existing stockholders were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under Rule 144, Rule 144(k) or Rule 701 under the Securities Act, which rules are summarized below.

As a result of the lock-up agreements described below and the provisions of Rule 144, Rule 144(k) and Rule 701 under the Securities Act, the shares of our common stock (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

- 4,159,206 shares will be eligible for sale under Rule 144(k) or Rule 701 upon the expiration of the lock-up agreements, as more particularly and except as described below, beginning 180 days after the date of this prospectus;
- 17,886,334 shares will be eligible for sale under Rule 144 upon the expiration of the lock-up agreements, as more particularly and except as described below, beginning 180 days after the date of this prospectus;
- 441,480 shares will be eligible for sale, upon exercise of vested options, upon the expiration of the lock-up agreements, as more particularly and except as described below, beginning 180 days after the date of this prospectus; and
- 96,250 shares will be eligible for sale, upon exercise of outstanding warrants, upon the expiration of the lock-up agreements, as more particularly and except as described below, beginning 180 days after the date of this prospectus.

Lock-up Agreements

We, each of our directors and executive officers, and all of the holders of our common stock and holders of securities exercisable for or convertible into shares of our common stock have each agreed not to sell or otherwise dispose of, directly or indirectly any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock for a period of not less than 180 days from the date of this prospectus without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated.

Merrill Lynch, in its sole discretion, at any time or from time to time and without notice, may release for sale in the public market all or any portion of the shares restricted by the terms of the lock-up agreements. The lock-up restrictions will not apply to transactions relating to common shares acquired in open market transactions after the closing of this offering provided that no filing by the transferor under Rule 144 of the Securities Act or Section 16 of the Exchange Act is required or will be voluntarily made in connection with such transactions. The lock-up restrictions also will not apply to certain transfers not involving a disposition for value, provided that the recipient agrees to be bound by these lock-up

restrictions and provided that no filing by the transferor under Rule 144 of the Securities Act or Section 16 of the Exchange Act is required or will be voluntarily made in connection with such transfers.

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of this offering, a person (or persons whose shares are required to be aggregated) who has beneficially owned restricted securities for at least one year, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- one percent of the number of common shares then outstanding, which will equal approximately 280,455 shares immediately after this offering (assuming no exercise of the underwriters' overallotment option and no exercise of outstanding options or warrants); or
- the average weekly trading volume of our common shares on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales of restricted shares under Rule 144 are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates that sell our common shares that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Rule 144(k)

Under Rule 144(k), a person who is not deemed to have been our affiliate at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate, may sell those shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquires common stock from us in connection with a compensatory stock or option plan or other written agreement before the effective date of this offering (to the extent such common stock is not subject to a lock-up agreement) is entitled to resell such shares 90 days after the effective date of this offering in reliance on Rule 144. The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the lock-up agreements described above, beginning 90 days after the date of this prospectus, may be sold by persons other than affiliates, as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by affiliates under Rule 144 without compliance with its one-year minimum holding period requirement.

Stock Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register shares of our common stock issued or reserved for issuance under our 2006 Equity Incentive Award Plan. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above.

Warrants

As of June 30, 2006, warrants to purchase a total of 385,000 shares of our Series A-2 preferred stock at a price of $1.00 per share were outstanding. Upon completion of this offering, these warrants will become exercisable for a total of 96,250 shares of our common stock at a price of $4.00 per share. See "Description of Capital Stock — Warrants." All of these common shares are subject to the terms of the lock-up agreements with the underwriters.

Stock Options

As of June 30, 2006, options to purchase a total of 1,442,372 shares of our common stock were outstanding, of which 1,354,797 were exercisable. All of the shares subject to options are subject to the terms of the lock-up agreements with the underwriters. An additional 419,693 shares of common stock were available for future option grants under our stock plan.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS TO NON-U.S. HOLDERS

This section summarizes material U.S. federal income tax considerations relating to the ownership and disposition of common stock to non-U.S. holders. This summary does not provide a complete analysis of all potential tax considerations. The information provided below is based on existing authorities. These authorities may change, or the IRS might interpret the existing authorities differently. In either case, the tax considerations of owning or disposing of common stock could differ from those described below. For purposes of this summary, a "non-U.S. holder" is any beneficial owner of our common stock other than a citizen or resident of the United States, a corporation or a partnership organized under the laws of the United States or any state, a trust that is (i) subject to the primary supervision of a U.S. court and the control of one of more U.S. persons or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person, or an estate whose income is subject to U.S. income tax regardless of source. If a partnership or other flow-through entity is a beneficial owner of common stock, the tax treatment of a partner in the partnership or an owner of the entity will depend upon the status of the partner or other owner and the activities of the partnership or other entity. Accordingly, partnerships and flow-through entities that hold our common stock and partners or owners of such partnerships or entities, as applicable, should consult their own tax advisors. The summary generally does not address tax considerations that may be relevant to particular investors because of their specific circumstances, or because they are subject to special rules, including, without limitation, banks, insurance companies, or other financial institutions; persons subject to the alternative minimum tax; tax exempt organizations; dealers in securities or currencies; traders in securities that elect to use a mark to market method of accounting for their securities holdings; persons that own, or are deemed to own, more than five percent of our company (except to the extent specifically set forth below); certain former citizens or long term residents of the United States; persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction; or persons deemed to sell our common stock under the constructive sale provisions of the Internal Revenue Code. Finally, the summary does not describe the effects of any applicable foreign, state or local laws.

INVESTORS CONSIDERING THE PURCHASE OF COMMON STOCK ARE URGED TO CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME AND ESTATE TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE CONSEQUENCES OF FOREIGN, STATE, OR LOCAL LAWS, AND TAX TREATIES.

Dividends

We have not made any distributions on our common stock, and we do not plan to make any distributions for the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current and accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed our current and accumulated earnings and profits, they will constitute a return of capital and will first reduce a non-U.S. holder's basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock. Any dividend paid to a non-U.S. holder on our common stock will generally be subject to U.S. withholding tax at a 30 percent rate. The withholding tax might not apply, however, or might apply at a reduced rate, under the terms of an applicable income tax treaty between the United States and the non-U.S. holder's country of residence. A non-U.S. holder must demonstrate its entitlement to treaty benefits by certifying its nonresident status. A non-U.S. holder can meet this certification requirement by providing a Form W-8BEN or appropriate substitute form to us or our paying agent. If the holder holds the stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such financial institution or the agent. The financial institution or the agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. For payments made to a foreign partnership or other flow-through entity, the certification requirements generally apply to the partners or other owners rather than to the partnership or other entity, and the partnership or other entity must provide the partners' or other owners' documentation to us or our paying agent. Special rules, described

below, apply if a dividend is effectively connected with a U.S. trade or business conducted by the non-U.S. holder.

Sale of Common Stock

Non-U.S. holders will generally not be subject to U.S. federal income tax on any gains realized on the sale, exchange, or other disposition of common stock. This general rule, however, is subject to several exceptions. For example, the gain would be subject to U.S. federal income tax if:

- the gain is effectively connected with the conduct by the non-U.S. holder of a U.S. trade or business (in which case the special rules described below apply);
- the non-U.S. holder is an individual who holds our common stock as a capital asset (generally, an asset held for investment purposes) and who is present in the U.S. for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met;
- the non-U.S. holder was a citizen or resident of the United States and thus is subject to special rules that apply to expatriates; or
- the rules of the Foreign Investment in Real Property Tax Act, or FIRPTA (described below) treat the gain as effectively connected with a U.S. trade or business.

An individual non-U.S. holder described in the second bullet point immediately above will be subject to a flat 30% tax on the gain derived from the sale, which may be offset by U.S. source capital losses, even though the individual is not considered a resident of the U.S. If a non-U.S. holder is described in the third bullet point above, the non-U.S. holder should consult its own tax advisor to determine the U.S. federal, state, local and other tax consequences that may be relevant to such holder.

The FIRPTA rules may apply to a sale, exchange or other disposition of common stock if we are, or were within five years before the transaction, a "U.S. real property holding corporation," or a USRPHC. In general, we would be a USRPHC if interests in U.S. real estate comprised most of our assets. We do not believe that we are a USRPHC or that we will become one in the future. If we are or become a USRPHC, so long as our common stock is regularly traded on an established securities market, only a non-U.S. holder who, actually or constructively, holds or held (at any time during the shorter of the five year period preceding the date of disposition or the holder's holding period) more than 5% of our common stock will be subject to U.S. federal income tax on the disposition of our common stock.

Dividends or Gain Effectively Connected With a U.S. Trade or Business

If any dividend on common stock, or gain from the sale, exchange or other disposition of common stock, is effectively connected with a U.S. trade or business conducted by the non-U.S. holder, then the dividend or gain will be subject to U.S. federal income tax at the regular graduated rates. If the non-U.S. holder is eligible for the benefits of a tax treaty between the United States and the holder's country of residence, any "effectively connected" dividend or gain would generally be subject to U.S. federal income tax only if it is also attributable to a permanent establishment or fixed base maintained by the holder in the United States. Payments of dividends that are effectively connected with a U.S. trade or business, and therefore included in the gross income of a non-U.S. holder, will not be subject to the 30 percent withholding tax. To claim exemption from withholding, the holder must certify its qualification, which can be done by filing a Form W-8ECI. If the non-U.S. holder is a corporation, that portion of its earnings and profits that is effectively connected with its U.S. trade or business would generally be subject to a "branch profits tax." The branch profits tax rate is generally 30 percent, although an applicable income tax treaty might provide for a lower rate.

Backup Withholding and Information Reporting

The Internal Revenue Code and the Treasury regulations require those who make specified payments to report the payments to the IRS. Among the specified payments are dividends and proceeds paid by brokers to their customers. The required information returns enable the IRS to determine whether the recipient properly included the payments in income. This reporting regime is reinforced by "backup withholding" rules. These rules require the payors to withhold tax from payments subject to information reporting if the recipient fails to cooperate with the reporting regime by failing to provide his taxpayer identification number to the payor, furnishing an incorrect identification number, or repeatedly failing to report interest or dividends on his returns. The withholding tax rate is currently 28 percent. The backup withholding rules do not apply to payments to certain exempt holders, including corporations, whether domestic or foreign, who establish their exempt status.

Payments to non-U.S. holders of dividends on common stock will generally not be subject to backup withholding, and payments of proceeds made to non-U.S. holders by a broker upon a sale of common stock will not be subject to information reporting or backup withholding, in each case so long as the non-U.S. holder certifies its nonresident status. Some of the common means of certifying nonresident status are described under "— Dividends." We must report annually to the IRS any dividends paid to each non-U.S. holder and the tax withheld, if any, with respect to such dividends. Copies of these reports may be made available to tax authorities in the country where the non-U.S. holder resides.

Any amounts withheld from a payment to a holder of common stock under the backup withholding rules can be credited against any U.S. federal income tax liability of the holder.

EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE, LOCAL, AND FOREIGN TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Pacific Growth Equities, LLC and JMP Securities LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in a purchase agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Merrill Lynch, Pierce, Fenner & Smith Incorporated	2,950,000
Deutsche Bank Securities Inc.	1,416,000
Pacific Growth Equities, LLC	1,003,000
JMP Securities LLC	531,000
Susquehanna Financial Group, LLLP	100,000
Total	6,000,000

Subject to the terms and conditions set forth in the purchase agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the purchase agreement if any of these shares are purchased. If an underwriter defaults, the purchase agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the purchase agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the purchase agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the initial public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $.37 per share. The underwriters may allow, and the dealers may reallow, a discount not in excess of $.10 per share to other dealers. After the initial public offering, the public offering price, concession and discount may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their overallotment option.

	Per Share	Without Option	With Option
Public offering price	$9.00	$54,000,000	$62,100,000
Underwriting discount	$.63	$3,780,000	$4,347,000
Proceeds, before expenses, to us	$8.37	$50,220,000	$57,753,000

The expenses of the offering, not including the underwriting discount, are estimated at $1.8 million and are payable by us.

Overallotment Option

We have granted an option to the underwriters to purchase up to 900,000 additional shares at the public offering price, less the underwriting discount. The underwriters may exercise this option for 30 days from the date of this prospectus solely to cover any overallotments. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the purchase agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We and our officers, directors, stockholders, warrant holders and option holders, who hold all of our shares of common stock, on a fully diluted basis, have agreed, subject to certain exceptions, not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch. Specifically, we and these other individuals have agreed not to directly or indirectly

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file a registration statement related to the common stock, or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock, whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lockup provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

Quotation on the Nasdaq Global Market

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "CADX."

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations among us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares in the offering. The underwriters may close out any covered short position by either exercising their overallotment option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the overallotment option. “Naked” short sales are sales in excess of the overallotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format will be made available on the websites maintained by one or more of the underwriters of this offering. Other than the electronic prospectus, the information on the websites of the underwriters is not part of this prospectus. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated to underwriters that may make Internet distributions on the same basis as other allocations.

Other Relationships

Some of the underwriters and their affiliates have provided from time to time, and may provide in the future, investment and commercial banking and financial advisory services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions.

LEGAL MATTERS

The validity of our common stock offered by this prospectus will be passed upon for us by Latham & Watkins LLP, San Diego, California. Latham & Watkins LLP and certain attorneys and investment funds affiliated with the firm collectively own an aggregate of 90,000 shares of our preferred stock, which will convert into an aggregate of 22,500 shares of our common stock upon the completion of this offering. Certain legal matters in connection with this offering will be passed upon for the underwriters by Heller Ehrman LLP, San Diego, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements as of December 31, 2004 and 2005 and for the period from May 26, 2004 (inception) through December 31, 2004 and for the year ended December 31, 2005 as set forth in their report. We have included our financial statements in this prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of our common stock offered hereby. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. Some items are omitted in accordance with the rules and regulations of the SEC. For further information with respect to us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus as to the contents of any contract, agreement or any other document are summaries of the material terms of this contract, agreement or other document. With respect to each of these contracts, agreements or other documents filed as an exhibit to the registration statement, reference is made to the exhibits for a more complete description of the matter involved. A copy of the registration statement, and the exhibits and schedules thereto, may be inspected without charge at the public reference facilities maintained by the SEC at 100 F Street NE, Washington, D.C. 20549. Copies of these materials may be obtained from the Public Reference Section of the SEC at 100 F Street NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facility. The SEC maintains a web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the SEC's website is http://www.sec.gov.

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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, 2004 and 2005 and the related statements of operations, stockholders' equity and cash flows for the period from May 26, 2004 (inception) through December 31, 2004 and for the year ended December 31, 2005. 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 on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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, 2004 and 2005 and the results of its operations and its cash flows for the period from May 26, 2004 (inception) through December 31, 2004 and for the year ended December 31, 2005 in conformity with generally accepted accounting principles in the United States.

/s/ Ernst & Young LLP

San Diego, California
April 21, 2006,
except for Note 10, as to which the date is
October 4, 2006.

Cadence Pharmaceuticals, Inc.
(a development stage company)

BALANCE SHEETS

	December 31, 2004	December 31, 2005	June 30, 2006 (Unaudited)	Pro Forma Stockholders' Equity at June 30, 2006 (Unaudited)
ASSETS				
Current assets:				
Cash and cash equivalents	$ 4,271,229	$ 8,025,285	$ 42,881,305	
Securities available-for-sale	—	7,000,000	—	
Prepaid expenses and other current assets	3,854	526,173	438,274	
Total current assets	4,275,083	15,551,458	43,319,579	
Property and equipment, net	108,735	117,740	770,693	
Restricted cash	—	—	1,581,130	
Other assets	457,159	222,000	805,405	
Total assets	$ 4,840,977	$ 15,891,198	$ 46,476,807	
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	$ 68,509	$ 715,781	$ 1,860,993	
Accrued liabilities	45,965	430,220	2,949,955	
Current portion of long-term debt	—	—	1,032,457	
Total current liabilities	114,474	1,146,001	5,843,405	
Deferred rent	—	—	116,309	
Long-term debt, less current portion	—	—	5,967,543	
Commitments				
Stockholders' equity:				
Preferred stock, $0.0001 par value:				
Series A-1 convertible preferred stock, 8,085,108 shares authorized, issued and outstanding at December 31, 2004 and 2005 and June 30, 2006 (unaudited); aggregate liquidation preference of $7,600,002; no shares issued and outstanding pro forma (unaudited)	809	809	809	$ —
Series A-2 convertible preferred stock, 12,900,001 shares, 17,675,347 shares and 18,060,347 shares authorized at December 31, 2004 and 2005 and June 30, 2006 (unaudited), respectively; no shares, 17,675,347 shares and 17,675,347 shares issued and outstanding at December 31, 2004 and 2005 and June 30, 2006 (unaudited), respectively; aggregate liquidation preference of $17,675,347; no shares issued and outstanding pro forma (unaudited)	—	1,767	1,767	—
Series A-3 convertible preferred stock, 53,870,000 shares authorized at June 30, 2006 (unaudited); 53,870,000 shares issued and outstanding at June 30, 2006 (unaudited); aggregate liquidation preference of $53,870,000; no shares issued and outstanding pro forma (unaudited)	—	—	5,387	—
Common stock, $0.0001 par value; 33,000,000 shares, 40,000,000 shares and 100,000,000 shares authorized at December 31, 2004 and 2005 and June 30, 2006 (unaudited), respectively; 1,170,000 shares, 1,904,000 shares and 2,137,935 shares issued and outstanding at December 31, 2004 and 2005 and June 30, 2006 (unaudited), respectively; 22,045,540 shares issued and outstanding pro forma (unaudited)	117	190	214	2,205
Additional paid-in capital	7,562,814	25,472,880	80,524,107	80,530,079
Stock subscription receivable	—	(187,600)	—	—
Deficit accumulated during the development stage	(2,837,237)	(10,542,849)	(45,982,734)	(45,982,734)
Total stockholders' equity	4,726,503	14,745,197	34,549,550	$ 34,549,550
Total liabilities and stockholders' equity	$ 4,840,977	$ 15,891,198	$ 46,476,807	

See accompanying notes.

Cadence Pharmaceuticals, Inc.
(a development stage company)

STATEMENTS OF OPERATIONS

	Period from May 26, 2004 (Inception) Through December 31, 2004	Year Ended December 31, 2005	Six Months Ended June 30,		Period from May 26, 2004 (Inception) Through June 30, 2006
			2005 (Unaudited)	2006 (Unaudited)	(Unaudited)
Operating expenses:					
Research and development	$ 1,883,357	$ 6,126,226	$ 2,401,589	$ 33,663,970	$ 41,673,553
Marketing	41,114	240,361	142,501	316,541	598,016
General and administrative	877,146	1,411,810	539,914	1,967,980	4,256,936
Total operating expenses	2,801,617	7,778,397	3,084,004	35,948,491	46,528,505
Loss from operations	(2,801,617)	(7,778,397)	(3,084,004)	(35,948,491)	(46,528,505)
Other income (expense):					
Interest income	9,380	255,785	13,996	552,501	817,666
Interest expense	—	—	—	(43,895)	(43,895)
Impairment of investment securities	(45,000)	(183,000)	(183,000)	—	(228,000)
Total other income	(35,620)	72,785	(169,004)	508,606	545,771
Net loss	$ (2,837,237)	$ (7,705,612)	$ (3,253,008)	$ (35,439,885)	$ (45,982,734)
Basic and diluted net loss per share	$ (3.10)	$ (6.67)	$ (2.87)	$ (28.50)	
Shares used to compute basic and diluted net loss per share	914,589	1,155,879	1,131,716	1,243,500	
Pro forma basic and diluted net loss per share		$ (1.49)		$ (2.41)	
Shares used to compute pro forma basic and diluted net loss per share		5,162,132		14,677,785	

See accompanying notes.

Cadence Pharmaceuticals, Inc.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY
For the Period from May 26, 2004 (inception) through June 30, 2006

	Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series A-3 Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Stock Subscription Receivable	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	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	293,527	(187,600)	—	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	8,085,108	809	17,675,347	1,767	—	—	1,904,000	190	25,472,880	(187,600)	(10,542,849)	14,745,197
Exercise of common stock options for cash between $0.40 and $1.36 per share in January through June (unaudited)	—	—	—	—	—	—	233,935	24	281,168	—	—	281,192
Collection of stock subscription receivable (unaudited)	—	—	—	—	—	—	—	—	—	187,600	—	187,600
Issuance of Series A-3	—	—	—	—	53,870,000	5,387	—	—	53,769,626	—	—	53,775,013

preferred stock for cash at $1.00 per share, net of $94,987 of offering costs, in March (unaudited)												
Issuance of warrants in connection with loan and security agreement in February (unaudited)	—	—	—	—	—	—	—	—	313,572	—	—	313,572
Employee stock-based compensation recognized under SFAS No. 123(R) (unaudited)	—	—	—	—	—	—	—	—	686,861	—	—	686,861
Net loss and comprehensive loss (unaudited)	—	—	—	—	—	—	—	—	—	—	(35,439,885)	(35,439,885)
Balance at June 30, 2006 (unaudited)	8,085,108	$ 809	17,675,347	$1,767	53,870,000	$5,387	2,137,935	$ 214	$80,524,107	$ —	$(45,982,734)	$ 34,549,550

See accompanying notes.

Cadence Pharmaceuticals, Inc.
(a development stage company)

STATEMENTS OF CASH FLOWS

	Period from May 26, 2004 (Inception) Through December 31, 2004	Year Ended December 31, 2005	Six Months Ended June 30, 2005 (Unaudited)	Six Months Ended June 30, 2006 (Unaudited)	Period from May 26, 2004 (Inception) Through June 30, 2006 (Unaudited)
Operating activities					
Net loss	$ (2,837,237)	$ (7,705,612)	$ (3,253,008)	$ (35,439,885)	$ (45,982,734)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation	8,389	36,876	15,771	28,862	74,127
Stock-based compensation	811	—	—	686,861	687,672
Non-cash interest expense and impairment charges	45,000	183,000	183,000	41,665	269,665
Changes in operating assets and liabilities:					
Prepaid expenses and other assets	(56,013)	(470,160)	(260,033)	59,799	(466,374)
Accounts payable, accrued liabilities and deferred rent	114,474	1,031,527	1,157,612	3,510,041	4,656,042
Net cash used in operating activities	(2,724,576)	(6,924,369)	(2,156,658)	(31,112,657)	(40,761,602)
Investing activities					
Purchases of marketable securities	(450,000)	(7,000,000)	—	—	(7,450,000)
Maturities of marketable securities	—	—	—	7,000,000	7,000,000
Restricted cash	—	—	—	(1,581,130)	(1,581,130)
Purchases of property and equipment	(117,124)	(45,881)	(10,719)	(681,815)	(844,820)
Net cash provided by (used in) investing activities	(567,124)	(7,045,881)	(10,719)	4,737,055	(2,875,950)
Financing activities					
Proceeds from issuance of common stock, net	22,500	106,000	109,000	456,609	585,109
Proceeds from sale of preferred stock, net of issuance costs	7,540,429	17,618,306	13,661,958	53,775,013	78,933,748
Borrowings under debt agreements	—	—	—	7,000,000	7,000,000
Net cash provided by financing activities	7,562,929	17,724,306	13,770,958	61,231,622	86,518,857
Increase in cash and cash equivalents	4,271,229	3,754,056	11,603,581	34,856,020	42,881,305
Cash and cash equivalents at beginning of period	—	4,271,229	4,271,229	8,025,285	—
Cash and cash equivalents at end of period	$ 4,271,229	$ 8,025,285	$ 15,874,810	$ 42,881,305	$ 42,881,305
Supplemental schedule of non-cash investing and financing activities					
Issuance of warrants in connection with loan and security agreement	$ —	$ —	$ —	$ 313,572	$ 313,572

See accompanying notes.

Cadence Pharmaceuticals, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS
(Information as of June 30, 2006 and thereafter and for the six months ended June 30, 2005 and 2006 and the period from May 26, 2004 (inception) through June 30, 2006 is unaudited)

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.

Unaudited Interim Financial Statements

The accompanying unaudited interim balance sheet as of June 30, 2006, the statements of operations and cash flows for the six months ended June 30, 2005 and 2006 and the period from May 26, 2004 (inception) through June 30, 2006 and the statement of stockholders' equity for the six months ended June 30, 2006 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company's financial position as of June 30, 2006 and results of operations and cash flows for the six months ended June 30, 2005 and 2006. The results of operations for the six months ended June 30, 2006 are not necessarily indicative of the results to be expected for the year ending December 31, 2006 or for any other interim period or for any other future year.

Unaudited Pro Forma Stockholders' Equity

The unaudited pro forma stockholders' equity information in the accompanying balance sheet assumes the conversion of the outstanding shares of convertible preferred stock at June 30, 2006 into 19,907,605 shares of common stock as though the completion of the initial public offering contemplated by the filing of this prospectus had occurred on June 30, 2006. Common shares issued in such initial public offering and any related estimated net proceeds are excluded from such pro forma information.

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.

Cadence Pharmaceuticals, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)
(Information as of June 30, 2006 and thereafter and for the six months ended June 30, 2005 and 2006 and the period from May 26, 2004 (inception) through June 30, 2006 is unaudited)

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, 2004 and 2005 and June 30, 2006, the carrying value of the investments approximated their fair market 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

Cadence Pharmaceuticals, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)
(Information as of June 30, 2006 and thereafter and for the six months ended June 30, 2005 and 2006 and the period from May 26, 2004 (inception) through June 30, 2006 is unaudited)

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 June 30, 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 June 30, 2006, research and development expenses relate predominantly to the in-licensing of IV APAP and Omigard and clinical trials for 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 is 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

Cadence Pharmaceuticals, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)
(Information as of June 30, 2006 and thereafter and for the six months ended June 30, 2005 and 2006 and the period from May 26, 2004 (inception) through June 30, 2006 is unaudited)

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.

During the six months ended June 30, 2006, the Company recorded $686,861, or $0.55 per share, of stock-based compensation expense as a result of the adoption of SFAS No. 123(R). Of this amount, the Company allocated $110,339, $84 and $576,438 to research and development, sales and marketing and general and administrative expenses, respectively, based on the department to which the associated employee reports. No related tax benefits of the stock-based compensation costs have been recognized since the inception of the Company.

The following table shows the assumptions used to compute the stock-based compensation costs for the stock options granted during the six months ended June 30, 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)	6.06 – 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 values of stock options granted during the six months ended June 30, 2006 was $5.90 per share.

As of June 30, 2006, the Company has approximately $7,500,000 of unrecognized stock-based compensation costs related to the non-vested balance of the 1,387,303 stock options granted during the six months ended June 30, 2006 and expects to recognize such compensation over a weighted average period of 3.66 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

Cadence Pharmaceuticals, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)
(Information as of June 30, 2006 and thereafter and for the six months ended June 30, 2005 and 2006 and the period from May 26, 2004 (inception) through June 30, 2006 is unaudited)

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 June 30, 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 Income

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, shall be reported, net of their related tax effect, to arrive at comprehensive income. The net loss and comprehensive loss were the same for all periods presented.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The unaudited pro forma basic and diluted net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period plus the weighted average number of common shares resulting from the assumed conversion of the outstanding shares of convertible preferred stock. The assumed conversion is calculated using the as-if-converted method, as if such conversion had occurred as of the beginning of each period presented or as of the original issuance date, if later.

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	Period from May 26, 2004 (Inception) Through December 31, 2004	Year Ended December 31, 2005	Six Months Ended June 30, 2005	Six Months Ended June 30, 2006
Historical				
Numerator:				
Net loss	$ (2,837,237)	$ (7,705,612)	$ (3,253,008)	$ (35,439,885)
Denominator:				
Weighted average common shares outstanding	920,137	1,319,367	1,192,514	1,956,706
Weighted average unvested common shares subject to repurchase	(5,548)	(163,488)	(60,798)	(713,206)
Weighted average common shares outstanding	914,589	1,155,879	1,131,716	1,243,500
Basic and diluted net loss per share	$ (3.10)	$ (6.67)	$ (2.87)	$ (28.50)
Pro Forma				
Net loss used above		$ (7,705,612)		$ (35,439,885)
Pro forma basic and diluted net loss per share		$ (1.49)		$ (2.41)
Shares used above		1,155,879		1,243,500
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock		4,006,253		13,434,285
Pro forma shares used to compute basic and diluted net loss per share		5,162,132		14,677,785
Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation				
Preferred stock (as converted)	2,021,271	6,440,107	5,477,607	19,907,605
Preferred stock warrants (as converted)	—	—	—	96,250
Common stock options	261,250	289,000	241,250	1,442,372
Common stock subject to repurchase	42,188	691,969	307,188	860,064
	2,324,709	7,421,076	6,026,045	22,306,291

2. Securities Available-for-Sale

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

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In addition, as of December 31, 2004 and 2005 and June 30, 2006, the Company held 617,284 shares of Migenix common stock acquired in July 2004 at an initial cost of $450,000. See Note 6 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, 2004	December 31, 2005	June 30, 2006
Leasehold improvements	2 years	$ 1,146	$ 1,146	$ 1,146
Computer equipment and software	3 years	55,245	63,972	186,006
Furniture and equipment	5 years	60,733	94,982	94,982
Manufacturing equipment	7 years	—	—	122,500
Construction in-process	—	—	—	437,281
		117,124	160,100	841,915
Less accumulated depreciation		(8,389)	(42,360)	(71,222)
		$ 108,735	$ 117,740	$ 770,693

4. Related Party Transactions

From September 2004 through August 2005, the Company paid Mr. 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 period from May 26, 2004 (inception) through December 31, 2004, the year ended December 31, 2005, the six months ended June 30, 2005 and 2006 and the period from May 26, 2004 (inception) through June 30, 2006, the Company expensed $20,000, $60,000, $30,000, $43,333, and $123,333, respectively for payments to Mr. Garner for services as chairman of the Company's board of directors. The unpaid balance as of December 31, 2004 and 2005 and June 30, 2006 was $20,000, $10,000 and $8,333, 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 6). The advance was accounted for in accordance with the SEC SAB Topic 5T (SAB No. 79), *Accounting for Expenses or Liabilities*

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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.

5. 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 conjunction 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. Excluding certain mergers or acquisitions, the warrants expire upon the later of: (a) 10 years from issuance or (b) five years after the closing of an initial public offering of the Company's common stock. 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 expires in September 2006. As of December 31, 2005 and June 30, 2006, the sublessor held a security deposit of $50,685. In May 2006, the Company entered into a six-year operating lease for 23,494 square feet of office space. The Company will receive 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

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the first four anniversaries of the commencement of the lease. Rent expense was $67,579, $190,911, $89,542, $274,231 and $309,174 for the period from May 26, 2004 (inception) through December 31, 2004, the year ended December 31, 2005, the six months ended June 30, 2005 and 2006 and the period from May 26, 2004 (inception) through June 30, 2006, respectively. As of June 30, 2006, future minimum payments under the operating leases total $186,999, $1,009,000, $1,074,851, $1,112,206, $1,151,676, $1,191,851 and $917,676 for the years ending December 31, 2006, 2007, 2008, 2009, 2010, 2011 and 2012, respectively.

6. 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. 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 expects to initiate Phase III clinical trials for the licensed product in 2006 but does not expect FDA approval prior to 2008. Accordingly, all payments related to the BMS agreement have been recorded as research and development expense.

7. Stockholders’ Equity

Convertible Preferred Stock

In July and August 2004, the Company issued 8,085,108 shares of Series A-1 preferred stock at $0.94 per share for cash of $7,600,002. The Company incurred offering costs of $59,573 resulting in net cash proceeds of $7,540,429.

In June and September 2005, the Company issued an aggregate of 17,675,347 shares of Series A-2 preferred stock at $1.00 per share for cash of $17,675,347. The Company incurred offering costs of $57,041 resulting in net cash proceeds of $17,618,306.

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In March 2006, the Company issued 53,870,000 shares of Series A-3 preferred stock at $1.00 per share for cash of $53,870,000. The Company incurred offering costs of $94,987 resulting in net cash proceeds of $53,775,013.

Each holder of Series A-1, A-2 and A-3 preferred stock has the right, at the option of the holder at any time, to convert shares of preferred stock into shares of common stock at a conversion ratio of one-to-four, subject to further adjustment for stock splits, certain capital reorganizations and dilutive stock issuances. Each share of preferred stock will automatically convert into shares of common stock, at the then effective applicable conversion rate upon the earlier of: (i) the day preceding the closing of the sale of the Company's common stock in connection with a firmly underwritten public offering in which the Company receives gross proceeds of at least $30,000,000 at a price of at least $12.00 per share (as adjusted from time to time) or (ii) the consent of at least 60% of the then outstanding shares of preferred stock, as a single class.

Unless 60% of the Series A-3 preferred stockholders vote otherwise, certain Series A-3 preferred stockholders that fail to participate in future equity financings up to specified amounts will lose their right of first offer related to any subsequent equity financings and any Series A-1 preferred stock held by them will automatically convert into newly created Series A-4 preferred stock and any Series A-2 and A-3 preferred stock held by them will automatically convert into newly created Series A-5 preferred stock. Series A-4 and A-5 preferred stock shall have identical rights and preferences as Series A-1, A-2 and A-3 preferred stock with the exception of certain anti-dilution protections.

The holders of Series A-1, A-2 and A-3 preferred stock are entitled to receive, when, as and if declared by the Company's Board of Directors out of legally available funds, non-cumulative dividends payable to holders of the preferred stock in an amount equal to $0.0752, $0.08 and $0.08 per share, respectively, in preference and priority to the payment of any dividends on common stock. As of December 31, 2005 and June 30, 2006, no dividends have been declared by the Board of Directors.

In the event of any liquidation, dissolution or winding up of the Company, the holders of Series A-1, A-2 and A-3 preferred stock will be entitled to receive in preference to the holders of common stock, the amount of their original purchase price per share, plus declared and unpaid dividends, if any. If the assets and funds available to be distributed among the holders of the preferred stock shall be insufficient to permit the payment to such holders of the full preferences, then the entire assets and funds legally available for distribution to such holders shall be distributed ratably based on the total due each such holder. Any remaining assets of the Company will be distributed ratably among the holders of the common stock and preferred stock, with the preferred stock limited to the aggregate of three times the original purchase price per share, based upon the number of shares of common stock held by each stockholder, treating each share of preferred stock as if it were converted into shares of common stock at the then-applicable conversion rate.

Preferred stockholders are entitled to the number of votes they would have upon conversion of their preferred shares into common stock at the then-applicable conversion rate. The preferred stockholders have been granted certain rights with regard to the election of board members and various other corporate actions.

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Stock Options

In 2004, the Company adopted the Cadence Pharmaceuticals, Inc. 2004 Equity Incentive Plan (the "2004 Plan"). The 2004 Plan allows for the grant of options, restricted stock awards, performance share awards, dividend equivalents, restricted stock units, stock payments and stock appreciation rights to employees, directors and consultants of the Company. As of December 31, 2005 and June 30, 2006, respectively, the 2004 Plan had 1,125,000 and 2,875,000 shares of common stock reserved for issuance. Options granted under the 2004 Plan expire no later than 10 years from the date of grant. Options generally vest over a four-year period and may be immediately exercisable. 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 be no less than 110% of the fair value of the Company's common stock on the date of grant. The fair value of the Company's common stock is established contemporaneously by the Company's board of directors all of whom are related parties. From May 26, 2004 (inception) through February 2006 the valuations were performed by the Company's board of directors who have experience in valuing early stage companies.

The Company has applied the guidance in the American Institute of Certified Public Accountants ("AICPA") Audit and Accounting Practice Aid Series, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, to determine the fair value of its 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, the Company is at an early stage of existence, primarily focused on product development with an unproven business model. To date, the Company has 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, the Company was considered to be in a very early stage of development as defined in the AICPA guidance where the preferences of the preferred stockholders, in particular the liquidation preferences, are very meaningful and the common stock was valued at $0.40 per share. Subsequent to the Company's licensing of IV APAP but prior to the initiation of the Company's initial public offering process on June 14, 2006, the Company allocated additional enterprise value to its common stock with an increase in the common stock valuation to $1.36 per share. Subsequent to the initiation of the initial public offering process, the Company increased its common stock valuation to $3.20 per share.

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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, less a marketability discount of 40% and 30%, respectively, which reflects the estimated risk of not completing the initial public offering.

At December 31, 2005 and June 30, 2006, respectively, a total of 57,000 and 419,693 shares of common stock remained available for issuance under the 2004 Plan. A summary of the Company's stock option activity under the 2004 Plan and related information are as follows:

	Options Outstanding	Weighted Average Exercise Price
Granted	306,250	$ 0.40
Exercised	(45,000)	$ 0.40
Balance at December 31, 2004	261,250	$ 0.40
Granted	769,250	$ 0.40
Exercised	(741,500)	$ 0.40
Balance at December 31, 2005	289,000	$ 0.40
Granted	1,387,307	$ 1.72
Exercised	(233,935)	$ 1.20
Balance at June 30, 2006	1,442,372	$ 1.52

	December 31, 2005				
	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.40	289,000	9.24	$ 0.40	247,380	$ 0.40

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	June 30, 2006					
	Options Outstanding			Options Exercisable		
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$0.40	254,250	8.72	$ 0.40	213,100	8.69	$ 0.40
$1.36	928,622	9.86	$ 1.36	890,447	9.86	$ 1.36
$3.20	259,500	9.96	$ 3.20	251,250	9.96	$ 3.20
	1,442,372	9.68	$ 1.52	1,354,797	9.70	$ 1.55

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 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 was $6.60 per share and $7.70 per share, respectively.

As of December 31, 2005 and June 30, 2006, respectively, 46,703 and 85,445 of the outstanding options under the 2004 plan were vested and 691,969 and 860,062 of the options exercised were subject to repurchase by the Company since they were unvested.

The aggregate fair value of options that vested during the six months ended June 30, 2006 was approximately $79,000. The aggregate intrinsic value of options exercised during the six months ended June 30, 2006 was approximately $1,500,000.

The aggregate intrinsic value of options outstanding and options exercisable as of June 30, 2006 was approximately $13,700,000 and $12,800,000, respectively.

Shares Reserved For Future Issuance

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

	December 31, 2005	June 30, 2006
Conversion of preferred stock	6,440,107	19,907,605
Common stock options granted and outstanding	289,000	1,442,372
Preferred stock warrants outstanding	—	96,250
Common stock options reserved for future issuance	57,000	419,693
	6,786,107	21,865,920

8. Income Taxes

Significant components of the Company's deferred tax assets for federal and state income taxes at December 31, 2004 and 2005 are shown below. A valuation allowance has been established as realization

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of such deferred tax assets has not met the more likely than not threshold requirement under SFAS No. 109.

	December 31, 2004	December 31, 2005
Deferred tax assets:		
Net operating loss carryforwards	$ 361,000	$ 3,528,000
Tax credit carryforwards	29,000	359,000
Capitalized research and development	591,000	520,000
Other, net	157,000	111,000
Total deferred tax assets	1,138,000	4,518,000
Valuation allowance for deferred tax assets	(1,138,000)	(4,518,000)
Net deferred taxes	$ —	$ —

At December 31, 2005, the Company had federal and state net operating loss carryforwards of approximately $8,659,000 and $8,663,000, 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 $283,000 which will begin expiring in 2024 unless previously utilized. The Company had state research and development tax credit carryforwards of approximately $116,000, 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.

9. 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, 2005 and June 30, 2006, the Company had not elected to make any contributions to the plan.

10. Subsequent Events

Stock Split

On October 4, 2006, the Company's board of directors 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.

Severance Obligations

In September 2006, Kenneth R. Heilbrunn, M.D., our former Senior Vice President, Clinical Development, resigned. In accordance with the terms of his employment agreement, the Company is 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 allows for the acceleration of vesting for those options that would vest one year from the date of termination. The Company will record a charge for the termination payments and accelerated vesting of options which total approximately $500,000.

Through and including November 18, 2006 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

6,000,000 Shares

Common Stock

PROSPECTUS

Merrill Lynch & Co.
Deutsche Bank Securities
Pacific Growth Equities, LLC
JMP Securities

October 24, 2006