ANNUAL REPORT 2006

Key Events in 2006

Amoxicillin PULSYS

- Study enrollment in our Phase III clinical trial for Amoxicillin PULSYS for the treatment of adolescents and adults with strep throat concluded on May 31, 2006, with a total of 620 patients.
- On August 10, 2006, we announced that our Amoxicillin PULSYS Phase III clinical trial achieved its desired clinical and microbiological endpoints. The trial demonstrated statistical non-inferiority of Amoxicillin PULSYS therapy versus an approved comparator therapy. The trial also demonstrated Amoxicillin PULSYS reached 85 percent bacterial eradication for the "per protocol" group of patients, in accordance with FDA guidance for product approval as first-line pharyngitis therapy.
- Based on the successful Phase III trial data, we submitted a New Drug Application (NDA) for Amoxicillin PULSYS on December 14, 2006.
- On February 12, 2007, we received a "refusal to file" letter from the FDA for our Amoxicillin PULSYS NDA, requesting additional information on our planned commercial manufacturing processes.
- We met with the FDA on February 26, 2007, to discuss the issues raised in their letter and reached agreement on what additional information is required for the filing to be accepted. We resubmitted our revised Amoxicillin PULSYS NDA providing the required additional information on March 23, 2007.

Marketed Products – Keflex® Capsules (Cephalexin USP)

- On May 12, 2006, the FDA approved our supplemental NDA for two new strengths of our Keflex antibiotic – 333mg and 750mg Keflex capsules.
- In June 2006, we announced that we entered into an agreement with a third party to provide us contract sales and marketing services in support of the new Keflex 750mg strength. Terms of the agreement include the training, hiring, and deployment of 75 contract sales representatives targeting high Keflex-prescribing physicians across the United States.
- Our contract sales representatives began directly promoting Keflex 750mg capsules to targeted physicians as well as providing patient starter samples in late July 2006.

Keflex PULSYS Development

- We continued development work on a PULSYS® version of Keflex, completing four additional Phase I studies during 2006, evaluating the pharmacokinetic profiles of various combinations of pulsatile cephalexin formulations.

Advancis Corporate Name Change

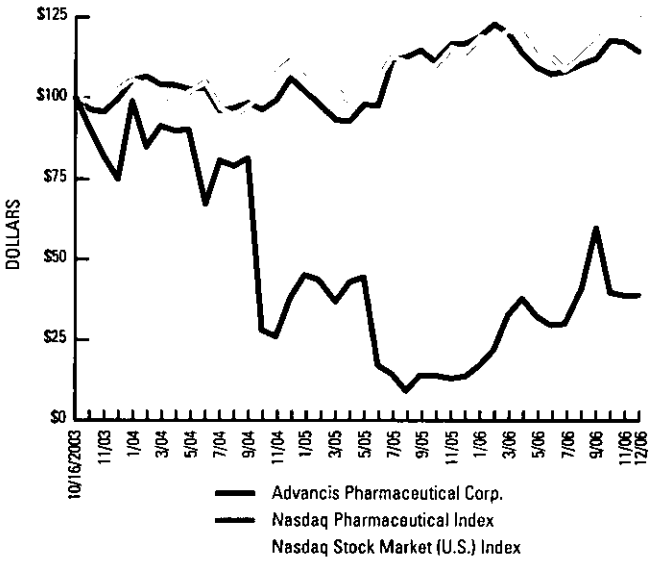
- In October 2006, we jointly submitted a proposed Permanent Injunction and Order with sanofi-aventis, pursuant to a U.S. Court Opinion and Order issued September 26, 2006, ruling that the Advancis corporate name is infringing the sanofi-aventis trademark. Following this joint submission, we have been actively involved in the process of selecting a new corporate name. We have made significant progress to date and expect to effect an orderly transition to our new corporate identity in the first half of 2007.

Financial Transactions

- On June 30, 2006, we closed a $12 million secured credit facility with Merrill Lynch Capital, consisting of an $8 million term loan and a $4 million revolving loan facility. The term loan was drawn in its entirety at closing, and matures in three years. The revolving loan facility matures 45 months from the closing date, and credit available under this facility will be determined based on a percentage of our accounts receivable.
- In December 2006, we completed a private placement of 6,000,000 shares of our common stock at a price of $3.00 per share, resulting in net proceeds to us, after the deduction of fees and commissions, of $16.7 million.

Stock Performance Graph

The following graph shows the cumulative total return resulting from a hypothetical $100 investment in our common stock on October 16, 2003, the date of our initial public offering, through December 31, 2006. Advancis stock price performance over this period is compared to the same amount invested in the Nasdaq Stock Market (U.S.) Index and the Nasdaq Pharmaceutical Index over the same period (in each case, assuming reinvestment of dividends). This graph is presented as required by SEC rules. Past performance might not be indicative of future results. While total stockholder return can be an important indicator of corporate performance, we believe it is not necessarily indicative of our corporation's degree of success in executing our business plan, particularly over short periods.



	10/16/03	12/31/03	12/31/04	12/31/05	12/31/06
Advancis Pharmaceutical Corp.	$100.00	$75.00	$38.20	$13.80	$39.10
Nasdaq Stock Market (U.S.)	$100.00	$102.66	$111.72	$114.10	$125.35
Nasdaq Pharmaceutical Index	$100.00	$99.75	$106.24	$116.99	$114.51

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2006

or

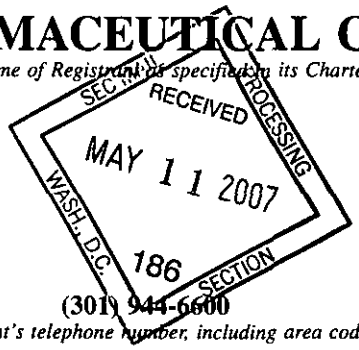
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 000-50414

ADVANCIS PHARMACEUTICAL CORPORATION

(Exact name of Registrant as specified in its Charter)



Delaware	**52-2208264**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. employer identification number)*
20425 Seneca Meadows Parkway Germantown, Maryland	**20876**
(Address of principal executive offices)	*(Zip Code)*

(301) 944-6600

(Registrant's telephone number, including area code)

None

(Former name, former address and former fiscal year — if changed since last report)

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

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, par value $0.01 per share**

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

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

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

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

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

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-accelerated Filer ☑

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

As of June 30, 2006, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $38,191,895.

As of February 26, 2007, 36,399,597 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Advancis Pharmaceutical Corporation's Notice of Annual Stockholder's Meeting and Proxy Statement, to be filed within 120 days after the end of the registrant's fiscal year, are incorporated by reference into Part III of this Annual Report.

ADVANCIS PHARMACEUTICAL CORPORATION

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FORM 10-K

FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K contains forward-looking statements, within the meaning of the Securities Exchange Act of 1934 and the Securities Act of 1933, that involve risks and uncertainties. In some cases, forward-looking statements are identified by words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may" and similar expressions. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. All of these forward-looking statements are based on information available to us at this time, and we assume no obligation to update any of these statements. Actual results could differ from those projected in these forward-looking statements as a result of many factors, including those identified in the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere. We urge you to review and consider the various disclosures made by us in this report, and those detailed from time to time in our filings with the Securities and Exchange Commission, that attempt to advise you of the risks and factors that may affect our future results.

PART I

Item 1. *Business*

Overview

We are a pharmaceutical company focused on developing and commercializing anti-infective drug products that fulfill substantial unmet medical needs in the treatment of infectious disease. We are developing a portfolio of drugs based on our novel biological finding that bacteria exposed to antibiotics in front-loaded, sequential bursts, or pulses, are killed more efficiently than those exposed to standard antibiotic treatment regimens. Based on this finding, we have developed a proprietary, once-a-day pulsatile delivery technology called PULSYS™ (PULSYS).

We have focused initially on developing PULSYS product candidates utilizing approved and marketed anti-infective drugs that no longer have patent protection or that have patents expiring in the next several years. Our lead PULSYS product candidate, based on the antibiotic amoxicillin, successfully completed a Phase III trial in 2006 and our New Drug Application (NDA) is currently under review by the U.S. Food and Drug Administration (FDA) in March 2007. Our Keflex PULSYS product candidate, based on the antibiotic cephalexin, is currently under evaluation in Phase I clinical trials. We also have a number of additional PULSYS product candidates in preclinical development. Preclinical product candidates will be prioritized and advanced into clinical trials based on their commercial opportunity and our level of financial and personnel resources. We are currently evaluating alternative financing options; however, absent a sufficient raise of additional capital, we may not be able to carry forward our anticipated product development initiatives. In order to minimize our financing requirements, we have initiated cost reductions including personnel reductions, postponement of PULSYS clinical development programs other than Amoxicillin PULSYS for adults, and elimination of other discretionary spending.

On August 10, 2006, we announced that our Phase III trial for Amoxicillin PULSYS in adults and adolescents with pharyngitis/tonsillitis (strep throat) had successfully met its desired endpoints. We enrolled a total of 620 patients into the trial through 50 sites in the United States and Canada, and believe it was the largest Phase III trial in pharyngitis/tonsillitis ever conducted in the United States. Following our prior unsuccessful Amoxicillin PULSYS Phase III trial in 2005, we decided to extend the length of treatment for our product candidate from seven days to 10 days.

Based on the results of our successful Phase III trial, we submitted a New Drug Application (NDA) for Amoxicillin PULSYS on December 14, 2006. On February 12, 2007, we received a "refusal to file" letter from the FDA, indicating that they required additional data on our proposed commercial manufacturing process in order to accept our application for filing. Following communications with the FDA clarifying the additional information that would be required for the FDA to accept our NDA for filing, we announced that we resubmitted our NDA for Amoxicillin PULSYS on March 23, 2007. We expect to receive a filing decision in May 2007. If the FDA accepts our application and approves the NDA on our target action date, we believe Amoxicillin PULSYS could be

marketed to healthcare professionals by as soon as early 2008. Our ability to commercially launch amoxicillin PULSYS on this time frame, or at all, will be dependent on our ability to raise additional capital.

We are currently evaluating commercialization options for our adult and adolescent Amoxicillin PULSYS product candidate. If we receive marketing approval, we expect to target high-volume prescribers with a community-based contract sales force detailing physicians, including family practitioners and internists. We are considering several sales and marketing strategies for Amoxicillin PULSYS, including working with contract sales organizations, developing our own internal sales organization, or co-promoting products with collaborative marketing partners.

On May 12, 2006, we received marketing approval from the FDA for two new strengths of our antibiotic Keflex® (cephalexin capsules, USP) — 333 mg and 750 mg capsules. We decided to commercialize only the 750 mg product. In July 2006, we began promoting Keflex 750 mg capsules to targeted physicians through a dedicated contract sales force of 75 sales representatives and eight Advancis district sales managers. We entered into an agreement with Innovex, the commercialization division of Quintiles Transnational Corp., to provide us contract sales and marketing services for the promotion of Keflex 750 mg capsules. We acquired the U.S. rights to Keflex from Eli Lilly in 2004, and are currently marketing 250 mg and 500 mg capsules in addition to the new 750 mg strength.

We believe our sales and marketing efforts with Keflex have enabled us to take important steps toward developing our in-house commercial capabilities which have the potential to be expanded with the possible launch of our Amoxicillin PULSYS products. In addition to our own sales and marketing efforts, we may also seek partners to assist in the marketing and sale of any our Keflex and/or amoxicillin products.

We began clinical studies for the development of a once-daily PULSYS version of Keflex in 2005, and completed four Keflex PULSYS Phase I clinical studies in 2006. We believe the added convenience of improving Keflex from its typical two to four times per day dosing regimen to a once-daily product can create an attractive commercial opportunity. In addition, we believe that the addition of a Keflex PULSYS product may allow us to further utilize any sales, marketing and distribution capabilities that we expect to have in place through the sales of existing Keflex products. Further development of Keflex PULSYS and/or our other product candidates, however, has been postponed and will proceed only if we secure additional capital resources.

In order for us to continue to execute our business plan, we will need to raise additional capital. We are currently evaluating alternative financing options; however, absent a sufficient raise of additional capital, we may not be able to carry forward our anticipated development initiatives.

We are evaluating various strategic alternatives to further enhance shareholder value, and in March 2007 we retained an investment banking firm to assist us in this regard. Strategic alternatives we may pursue could include, but are not limited to, continued execution of our operating plan, licensing or development arrangements, the sale of some or all of our company's assets, partnering or other collaboration agreements, or a merger or other strategic transaction. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

We were incorporated in Delaware in December 1999 and commenced operations in January 2000. Our principal executive offices are located at 20425 Seneca Meadows Parkway, Germantown, Maryland 20876. Our telephone number is (301) 944-6600. Our website is www.advancispharm.com. Information contained on our website is not part of, and is not incorporated into, this annual report on Form 10-K. Our filings with the SEC are available without charge on our website as soon as reasonably practicable after filing. Advancis, Advancis Pharmaceutical Corp., the Advancis logo, PULSYS, Keflex and the Keflex logo are trademarks and trade names of Advancis Pharmaceutical Corporation. All other trademarks, trade names or service marks appearing in this annual report on Form 10-K are the property of their respective owners. We are in the process of changing our corporate name, which will no longer include the word "Advancis". All trademarks, trade names and logos that include the word "Advancis" will be changed by June 30, 2007. See Item 3, *"Legal Proceedings"*, below for more information.

Market Opportunity

Infectious diseases are caused by pathogens such as bacteria, viruses and fungi that enter the body through the skin or mucous membranes of the lungs, nasal passages and gastrointestinal tract, and overwhelm the body's immune system. These pathogens establish themselves in various tissues and organs throughout the body and cause a number of serious and, in some cases, lethal infections.

We believe that the antibiotic market presents a highly attractive opportunity for the following reasons:

Substantial market. Antibiotics, along with antiviral medications and antifungal medications, constitute the primary categories of the anti-infectives market. According to sales data compiled by IMS Health, an independent pharmaceutical industry research firm, worldwide anti-infective sales were approximately $62.1 billion in 2005, including $26.1 billion in North America. Antibiotics accounted for approximately $34.6 billion of such 2005 worldwide sales, including more than $12.0 billion in North America *(IMS World Review 2005).*

Increased resistance to existing therapies. Certain medical, veterinary and agricultural practices and sociological factors have led to increased bacterial resistance to many currently available antibiotics. Bacterial resistance has been fostered through the erroneous prescription of anti-infective drugs for non-bacterial infections and unconfirmed infections and the administration of broad spectrum antibiotics before the specific disease-causing pathogen has been identified. In addition, the lack of patient compliance with prescribed course of therapies has contributed to bacterial resistance to currently marketed compounds. For example, it is estimated that one-third of all *Streptococcus pneumoniae*, a type of bacteria that can cause pneumonia, meningitis and ear infections are resistant to penicillin. The increased prevalence of resistant bacteria has resulted in prolonged hospitalizations, increased healthcare costs and higher mortality rates.

Growing need for improved new treatments. Social and demographic factors are contributing to the growth in the antibiotic market and the need for new, more effective therapies. The aging population of the United States is more likely to have suppressed immune systems and will require drugs that are effective against increasingly resistant strains of bacteria. Patients diagnosed with diseases that target the immune system, such as AIDS, increasingly require therapies that are more effective to combat infection. In addition, the pharmaceutical industry continues to develop therapeutics, such as cancer chemotherapy, that weaken the immune system as a side effect of the primary therapy. As a result, we believe there is a strong demand for new treatments that are more potent, more effective against resistant strains and that cause fewer side effects.

Difficulties in developing new classes of anti-infective compounds. We believe that the growing problem of resistance and other limitations of currently available antibiotics are not being adequately addressed. Moreover, many of the large pharmaceutical companies have reduced research and development efforts in this sector and others have stopped producing anti-infective products.

Limitations of standard treatment regimens. In addition to the increased incidence of antibiotic resistant bacteria, we believe that standard antibiotic treatment regimens have several other limitations, including multiple daily dosage requirements, lengthy treatment periods, limited effectiveness and severe side effects, all of which decrease patient compliance and ultimately, therapeutic efficacy.

Our Proprietary PULSYS Technology

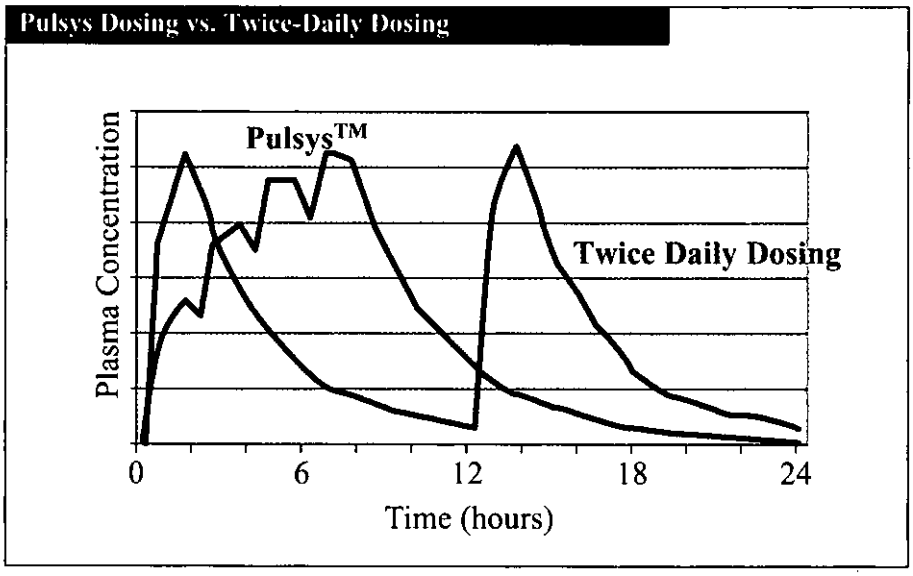
The significant unmet needs in the anti-infective market prompted our founders to search for a more efficient method to attack bacteria. In a series of seminal laboratory experiments, we observed that antibiotics such as amoxicillin can be more effective in killing bacteria when delivered in three to five discrete pulses of drug within the initial six to eight hours of a dosing interval. To take advantage of these experimental findings, we created a proprietary, once-a-day oral drug delivery technology called PULSYS™. PULSYS is designed to sequentially release specific portions of the drug dose, yielding a pulsatile pattern of antibiotic release. We believe that our novel finding, as implemented through our PULSYS technology, will potentially enable therapeutic advantages including:

- Improved bactericidal activity, or bacteria killing efficiency.

- Once-daily dosing and/or shorter length of treatment resulting in increased patient convenience and compliance.
- Lower overall drug dose with a possibly reduced side effect profile.
- Decreased emergence of antibiotic resistant bacteria.

Our approach to improving antibiotic effectiveness represents a departure from traditional methods, which have focused on increasing drug dosages and searching for new classes of drugs. Our pulsatile dosing approach attempts to increase antibiotic effectiveness by better exploiting vulnerabilities in the growth cycle and natural defense mechanisms of bacteria.

The graph below conceptually illustrates drug concentration profiles in a patient's bloodstream over a 24-hour period comparing drugs administered through our PULSYS system with standard twice daily dosing. The standard dosing regimen reflects the administration of an immediate release tablet at the start of a day, followed by an additional immediate release tablet 12 hours later. The PULSYS profile reflects the administration of a single dose designed to release the drug in four front-loaded pulses, with no additional doses administered for the balance of the day.



PULSYS is a proprietary method of administering a pharmaceutical agent such that the active ingredient is given in a front loaded, sequential pulse fashion. PULSYS can be realized or practiced by administering a solid oral dosage form that may contain multiple units, for example pellets, minitablets, etc. with varying release profiles that are combined in a proportion to produce optimum medication levels during the first few hours after dosing. PULSYS can also be realized as other dosage forms such as topicals, transdermals, insertables, etc. We anticipate that our pulsatile drug products could each provide for once-a-day dosing. We strive to utilize commonly-used inactive ingredients and common manufacturing processes when making PULSYS or any other type of anti-infective product. We are exploring the pulsatile administration of anti-infective agents in forms other than solid oral dosage forms.

PULSYS drug product candidates are evaluated using our proprietary design strategy. We are currently focusing on antibiotics, but also have proprietary positions in the antiviral, antifungal and antineoplastics fields. This approach combines computer simulations with microbiology and other laboratory experiments to analyze the physical, chemical, biological and microbiological properties of each specific antibiotic in order to optimize selection and design of pulsatile drug candidates. This analysis includes an evaluation of the physicochemical properties and metabolism profiles of antibiotics as a function of position in the gastro-intestinal tract. We attempt to optimize overall antibiotic bioavailability by adjusting the timing and composition of pulses. By examining the

bioavailability of antibiotics prior to the selection of PULSYS candidates, we believe that we will increase the likelihood of successful product development.

Our Strategy

We expect to use our novel finding and related proprietary technology to develop and commercialize more efficient, effective and convenient pharmaceutical products, with an initial focus on antibiotics. To achieve this objective, we have adopted the following product development and commercialization strategies:

Commercialize products with multiple advantages. We plan to develop PULSYS products that have multiple therapeutic advantages over currently available antibiotics, which may include once-daily dosing, lower doses, and in some cases, shorter treatment periods. We believe that these advantages will be further reflected with at least some of our PULSYS products in fewer dose-related side effects, reduced incidence of resistance and improved efficacy.

Focus initially on existing antibiotics. We anticipate reducing development risk and expense and decreasing time to market for our drug candidates by focusing on improved versions of approved and marketed drugs, either delivered alone or in combination with other drugs. The additional benefits of developing improved formulations of existing and approved antibiotics include reasonable and predictable production costs and higher probability of market acceptance due to the use of well-known antibiotics. In addition, since these existing products have already been proven to be safe and effective, we anticipate being able to rely on existing approvals and existing safety and efficacy data, which would allow us to reduce the amount of new data that we will need to generate in order to support FDA approval of our products.

Focus on first-line, broad-spectrum antibiotics for community infections. We are pursuing a product development strategy focused primarily on first-line, broad spectrum antibiotics for community infections. Our pulsatile antibiotic products are expected to target upper respiratory tract infections and skin and skin structure infections in particular. The target indications for our current product candidates cover some of the top antibiotics-related diagnoses and are intended to compete against the top most-prescribed antibiotics. We believe products utilizing our front-loaded, pulsed dosing approach will support once-daily dosing where two-to-four times daily dosing is the norm, with a concomitant reduction in dose and treatment duration (in some cases) compared to current traditional therapies.

Develop sales and marketing functions across multiple products. We intend to build over time, assuming we have sufficient capital resources, a pharmaceutical company which may include discovery, development, manufacturing, distribution, sales, and marketing capabilities. We believe that this commercialization strategy will allow us to fully maximize the value of our PULSYS product assets and retain significant control over our development and commercial activities. In support of the introduction of our first proprietary product, Amoxicillin PULSYS, we are considering several sales and marketing strategies, including the continued development of our own sales and marketing infrastructure. We believe that a significant proportion of prescriptions for first-line, broad-spectrum antibiotics is written by a relatively small number of high-volume prescribers who can be reached by a community-based sales force. Over time, we intend to expand our sales and marketing capabilities to provide even greater support of our target audiences. We also may enter into agreements with other pharmaceutical companies to exploit our partners' sales and marketing capabilities in order to optimally market our products.

Multi-level patent strategy. We have implemented a multi-level patent strategy in order to protect our anticipated pulsatile drug products. The first level is composed of "umbrella" patents and patent applications to protect the PULSYS administration of general classes of anti-infective drugs, such as antibiotics, antivirals, antifungals and antineoplastics The second level is composed of "sub-umbrella" patents and patent applications, protecting the PULSYS administration of subclasses of drugs, such as beta-lactam antibiotics with enzyme inhibitors. The third level includes patents and applications for specific anti-infective agents. We intend to continue to use and enhance this strategy in order to protect our intellectual property. We currently own 25 issued U.S. patents, 23 U.S. patent applications, and 2 issued foreign patents. Our issued patents cover certain compositions and methods for using pulsatile dosing. We also own 67 foreign-filed patent applications, which correspond to our U.S. patents and applications. We also own four International (PCT) patent applications, each of which

International (PCT) patent applications we anticipate converting into several individually foreign-filed patent applications to further correspond to our U.S. patents and applications.

License or acquire antibiotic products. We continue to explore pulsatile formulations for a wide range of other antibiotics and antibiotic combinations and, assuming we have sufficient financial resources, we may in-license or acquire antibiotic products that we believe can be improved with our novel pulsatile dosing approach.

Our Marketed Products

Keflex

On June 30, 2004, we acquired the U.S. rights to the Keflex brand of cephalexin from Eli Lilly and Company. The purchase price was $11.2 million, including transaction costs, which was paid in cash from our working capital. The asset purchase includes the exclusive rights to manufacture, sell and market Keflex in the United States (including Puerto Rico). We also acquired Keflex trademarks, technology and new drug applications (NDAs) supporting the approval of Keflex capsules and oral suspension. On December 9, 2004, we announced that we entered into a commercial supply agreement with Ceph International Corporation, a wholly owned subsidiary of Patheon's MOVA Pharmaceutical Corporation, to secure a long-term supply for Keflex products beyond the transitional period.

On May 12, 2006, the FDA approved two new strengths of Keflex for marketing — 750 mg and 333 mg capsules. We decided to focus our commercialization efforts solely on Keflex 750 mg capsules. We believe the introduction of Keflex 750 mg capsules will allow physicians the flexibility to deliver higher doses of Keflex with fewer capsules per day. In July 2006, we began promoting Keflex 750 mg capsules across the U.S. to targeted high-prescribing physicians through a dedicated national contract sales force of 75 sales representatives and eight Advancis district sales managers. While we have experienced growth in sales of Keflex 750mg capsules since its introduction, the rate of sales increase has not met our expectations, and we may pursue alternative Keflex sales and marketing strategies in 2007 in an effort to maximize the product's financial contribution to our company.

Keflex is a first-generation cephalosporin approved for treatment of several types of bacterial infections. Keflex is most commonly used in the treatment of uncomplicated skin and skin structure infections and, to a lesser extent, upper respiratory tract infections. Keflex is among the most prescribed antibiotics in the U.S., however, generic competition is intense, and a high percentage of all Keflex prescriptions are substituted by generic versions of cephalexin, the active ingredient in Keflex. We have the exclusive U.S. rights to manufacture, sell and market Keflex pursuant to our purchase agreement with Eli Lilly and Company. We market Keflex in the U.S. to healthcare practitioners, pharmacists, pharmaceutical wholesalers and retail pharmacy chains.

Keflex Products	Key Indication(s)	Status	Marketing Rights
Keflex Capsules — 250 mg, 333 mg, 500 mg, and 750 mg(1)	Skin and skin structure infections; upper respiratory tract infections	FDA-approved	U.S. and Puerto Rico rights

(1) On May 12, 2006, we received approval of our supplemental NDA (sNDA) to the Food & Drug Administration requesting marketing approval of Keflex 333 mg and 750 mg capsules.

In addition to our ongoing sales and marketing responsibilities for Keflex, we have initiated a research program with the goal of developing a once-a-day cephalexin product utilizing our proprietary once-a-day PULSYS dosing technology. In the event we are able to develop and commercialize a PULSYS-based Keflex product, other cephalexin products relying on the acquired NDAs, or other pharmaceutical products using the acquired trademarks, Eli Lilly will be entitled to royalties on these new products. Our Keflex 750 mg product (and our potential Keflex 333 product, should we decide to commercialize it) is subject to the royalty. Royalties are payable on a new product by new product basis for five years following the first commercial sale for each new product, up to a maximum aggregate royalty per calendar year. All royalty obligations with respect to any defined new product cease after the fifteenth anniversary of the first commercial sale of the first defined new product.

Our Product Pipeline

The following tables summarize the antibiotic compounds we have in clinical trials and preclinical development. We expect that these compounds will serve as the basis for drug products or, with additional clinical development, drug combination products. Each of our preclinical product candidates is still in the early stage of development and their further clinical progress requires significant additional capital expenditures that would be completely dependent upon our ability to obtain additional financing. Due to our on-going research and development efforts, additional or alternative compounds may be selected to replace or supplement the compounds described below.

PULSYS Product Candidate/Program	Key Indication(s)	Current Therapy	Targeted PULSYS Added Value	Program Status(1)
Amoxicillin — Adult	Pharyngitis/tonsillitis	10-14 days, two or three times daily	10 days, once-daily, lower dose	NDA submitted(2)
Keflex (cephalexin) — Adult	Skin and skin structure infections	7-14 days, two to four times daily	10 days, once-daily, lower dose,	Phase I (on hold)
Pediatric Pharyngitis Program	Pharyngitis/tonsillitis	10-14 days, two or three times daily	10-days, once-daily, lower dose, improved convenience	Phase I (on hold)

(1) For an explanation of the terms Preclinical, Phase I, Phase I/II and Phase III, please refer to the information under the heading "*Government Regulation*" below. Each of the product candidates above is discussed in more detail in the next section below.

(2) Our Amoxicillin PULSYS NDA has been submitted to and is currently being evaluated by the FDA. See "*Pulsatile Product Candidates — Amoxicillin* PULSYS" below.

A significant portion of our expenses are related to research and development of investigational stage product candidates. Please see *"Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations"* for a detailed discussion of our research and development expenses. In the event we are unable to raise additional capital, we may be forced to discontinue or alter our development programs.

Pulsatile Product Candidates

We intend to develop the pulsatile drugs listed above and those in preclinical development, with the intention of incorporating one or more of the following improvements:

- Once-a-day formulation
- Lower dose
- Shorter duration of therapy
- Reduced side effect profile
- Combination product with superior efficacy over either product alone
- Improved pediatric dosage form

Currently, our drug product candidates primarily represent improved versions of approved and marketed drugs, either delivered alone or in combination with other drugs. Since these existing drugs have already been approved for marketing by the FDA, we anticipate being able to rely, in part, on the FDA's prior findings on the safety and/or efficacy of these existing drugs in seeking FDA approval of our PULSYS products. Based on meetings with the FDA regarding the study program for our amoxicillin products, we filed a New Drug Application via the 505(b)(2) regulatory pathway for our Amoxicillin PULSYS product candidate, which, in part, relies on the FDA's prior findings regarding the safety and efficacy of amoxicillin.

Amoxicillin PULSYS

Amoxicillin (marketed by GSK as Amoxil and marketed by other companies as a generic product) is a semi-synthetic antibiotic that is effective for the treatment of a variety of conditions, including ear, nose and throat

infections, urinary tract infections, skin infections and lower respiratory infections. We believe the market opportunity for a once-daily Amoxicillin PULSYS product is substantial, with approximately 59 million prescriptions written for amoxicillin formulations in 2006 *(IMS National Prescription Audit 2006)*, making it the most widely prescribed antibiotic drug in the United States. In 2006, amoxicillin had U.S. retail sales of approximately $1.2 billion, based on branded retail pricing of $20 per prescription. Amoxicillin is generally recommended for dosing two or three times daily, for a period of ten to 14 days.

Our *in vitro* studies demonstrated that pulsatile dosing of amoxicillin had significantly better bacterial killing efficiency than standard regimens of amoxicillin (analogous to immediate release products taken twice daily or three-times daily) against a resistant strain of *Streptococcus pneumoniae*.

Our Amoxicillin PULSYS product candidate successfully concluded a re-designed Phase III clinical trial for the treatment of pharyngitis/tonsillitis for adults and adolescents using a 10-day treatment period in August 2006. We conducted our first Phase III clinical trial for adult pharyngitis in 2005, using a shorter 7-day duration of therapy, which failed to achieve its desired microbiological and clinical end points. If we receive FDA approval for our current 10-day therapy, Amoxicillin PULSYS may be the first and only once-daily amoxicillin treatment of pharyngitis/tonsillitis approved in the United States.

Our re-designed non-inferiority Phase III trial conducted in 2005/2006 enrolled 620 adult and adolescent patients in 50 centers in the U.S. and Canada. We compared our Amoxicillin PULSYS tablet for the treatment of pharyngitis/tonsillitis due to *S. pyogenes* (Group A streptococcus) delivered in a once-daily, 775 milligram tablet for a period of 10 days to 250 milligrams of penicillin dosed four times daily, for a total of one gram per day, for 10 days. Amoxicillin PULSYS demonstrated statistical non-inferiority to the comparator therapy in the trial's primary endpoints, which were eradication of all bacteria as determined during the post-therapy "test-of-cure" visit for patients who fully complied with the trial protocol, as well as in a larger patient population. Amoxicillin PULSYS also demonstrated non-inferiority in the trial's secondary endpoints, including clinical cure at the test-of-cure visit and bacterial eradication at the late post-therapy visit.

Today in the United States, the most frequently prescribed pharyngitis prescription is for 500 mg of amoxicillin three times daily for ten days, or 15 grams total over the course of therapy. In addition, amoxicillin is the most commonly mentioned antibiotic associated with the pharyngitis/tonsillitis diagnosis. Our Amoxicillin PULSYS product candidate for adults and adolescents is dosed 775 mg once-daily for ten days, or 7.75 grams total per course of therapy. Therefore, if we receive FDA approval and successfully launch the product, we would be able to dose approximately one-half the amount of amoxicillin, while also providing the convenience of once-daily dosing.

On December 14, 2006, we submitted a 505 (b) (2) New Drug Application to the FDA for our adult and adolescent Amoxicillin PULSYS product, based upon the data from our successfully concluded Phase III trial. On February 12, 2007, we received a "refusal to file" letter from the FDA, requesting additional information on our planned commercial manufacturing processes. In its letter, the FDA indicated that our application was not sufficiently complete in that it did not include a proposed commercial batch record or a detailed commercial process description with process parameters and in-process controls.

We conducted a meeting with the FDA regarding our Amoxicillin PULSYS NDA on February 26, 2007. In that meeting, we reached agreement with the FDA on the additional information that is required for our NDA filing to be accepted by the FDA. Based on the outcome of the FDA meeting, we resubmitted the NDA to the FDA for our adult and adolescent amoxicillin product on March 23, 2007. In accordance with FDA guidelines, the FDA has 60 days to preliminarily review the NDA filing and assess whether the application is acceptable for filing and substantive review.

We expect to receive a filing decision in May 2007, and if accepted for filing, to receive a FDA target action date in January 2008. Even if our Amoxicillin PULSYS product candidate is approved by the FDA, the earliest we could launch Amoxicillin PULSYS would be in early 2008. In addition, in order to successfully launch Amoxicillin PULSYS, we will need to have sufficient financial resources which will require us to raise additional capital. These forward-looking statements are based on information available to us at this time. Actual results could differ because of a delay in resubmission or due to delays in the FDA approval process. We cannot assure you that we will obtain FDA approval for this product or that, if approved, it will be approved within our anticipated time frame.

Keflex (Cephalexin) PULSYS

We are developing a once-daily PULSYS version of Keflex, our first generation oral cephalosporin antibiotic. Our intent is to develop a once-daily Keflex PULSYS for uncomplicated skin and skin structure infections. Currently, Keflex (or, in its generic form, cephalexin) is the antibiotic most frequently prescribed by physicians in the treatment of uncomplicated skin and skin structure infections. Most commonly, Keflex is prescribed 500 mg three times per day for a period of ten days. We believe a once-daily version of Keflex PULSYS may represent a substantial market opportunity. In 2006, cephalexin, the active ingredient in Keflex, was the third most prescribed antibiotic in the United States, with more than 24 million prescriptions *(IMS National Prescription Audit 2006)*. Assuming branded retail pricing of $30 per prescription, we estimate that the cephalexin market opportunity has a value of approximately $720 million.

We completed four Keflex PULSYS Phase I clinical studies in 2006, evaluating various pulsatile formulations of Keflex dosed in a total of more than 100 healthy volunteer subjects. Based on the results from our Phase I studies, we may finalize the formulation, daily dose, and duration of treatment for our Keflex PULSYS product candidate during 2007. We expect to meet with the FDA to gain agreement and to determine the required Phase III trial design and clinical development program to support a regulatory application for marketing approval of a Keflex PULSYS product candidate assuming we have sufficient financial resources. Should we decide to move forward with a pivotal Phase III trial for a Keflex PULSYS product, enrollment in such a Phase III trial could begin as early as the second half of 2007. These forward-looking statements are based on information available to us at this time. Actual results could differ because our trial results could be delayed or unsuccessful or due to delays in FDA approval, which may never occur.

We intend to utilize our current sales and marketing capabilities for our Keflex line of products in order to commercialize Keflex PULSYS, if it is approved by the FDA and we have sufficient capital and other resources. In addition, we may determine that in order to maximize the commercial potential of Keflex PULSYS, it may be advantageous to enter into agreements with other pharmaceutical companies to expand the sales and marketing effort supporting the product.

Pediatric Pharyngitis Program

We have developed two Amoxicillin PULSYS formulations, an adult formulation presented in a tablet, and a pediatric sprinkle. Our pediatric sprinkle product utilizes a similar formulation to the adult product; however, it is dosed in multiparticulate granules designed to be sprinkled over food. Survey results from patients and caregivers utilizing our pediatric sprinkle product suggest that its convenience and transportability may be beneficial features of our sprinkle formulation. Regardless of the antibiotic selected for our pediatric pharyngitis program, we expect to utilize our sprinkle presentation as the method of dosing our product. We believe the market opportunity for a pediatric strep throat product is substantial, as more than half of the strep throat market is believed to be represented by pediatric patients.

In 2005, we concluded a Phase III clinical trial evaluating once-daily Amoxicillin PULSYS in pediatric patients with pharyngitis/tonsillitis (strep throat) which failed to achieve its desired clinical endpoints. However, we believe there is potential for us to pursue a pulsatile version of amoxicillin, or another antibiotic, for the treatment of pediatric patients with strep throat through a redesigned clinical trial program. In 2006, we completed a Phase I study evaluating the observed drug concentrations from various pulsatile sprinkle amoxicillin formulations in healthy volunteer subjects. Based on the results from our Phase I studies, we may evaluate the safety and efficacy of various daily doses and durations of treatment for our pediatric Amoxicillin PULSYS product candidate in a Phase II study, should we have sufficient capital and other resources to do so.

Other Possible Pulsatile Product Candidates

Our current focus is on the antibiotic product candidates that include amoxicillin and Keflex. We have also identified additional product candidates which we believe could be developed for delivery in a pulsatile manner. The timing of further development work on these candidates depends on our resources as well as our evaluation of the commercial potential of the products.

PULSYS Preclinical Development Programs

Advancis has identified several additional opportunities to apply PULSYS technology to develop individual and combination antibiotic products which we believe could have application against the following indications:

- Sinusitis
- Chronic Bronchitis
- Acute Otitis Media
- Urinary Tract Infections
- Community-acquired Methicillin Resistant *Staphylococcus aureus* (MRSA).

We have conducted preclinical studies evaluating the bacterial killing efficiency of several antibiotics and antibiotic combinations dosed in a pulsatile manner. Based on these studies, along with the consultation of our scientific advisors, we believe we may be able to utilize our PULSYS technology in the creation of antibiotic product candidates that target some of the most common uses of antibiotics. These uses include: sinusitis, chronic bronchitis, acute otitis media, urinary tract infections, and community-acquired methicillin resistant *Staphylococcus aureus* (MRSA). We have currently placed all of these development programs on hold, and any plans for additional studies regarding these, or any other, possible product candidates will be dependent on our ability to raise sufficient capital to fund these types of studies.

We may also explore the use of our pulsatile dosing approach beyond antibiotics to other therapeutic categories, such as anti-virals and anti-fungals, in the event we have sufficient financial and other resources to do so. Although we have not tested the effectiveness of pulsatile dosing for these applications, we believe that our approach may yield benefits similar to those we have found for the treatment of bacterial infections.

Collaboration Agreements

Termination of Our Collaboration with Par Pharmaceutical for Amoxicillin PULSYS

In May 2004, we entered into an agreement with Par Pharmaceutical to collaborate in the further development and commercialization of a PULSYS-based amoxicillin product. Under the terms of the agreement, we conducted the development program, including the manufacture of clinical supplies and the conduct of clinical trials, and were responsible for obtaining regulatory approval for the product. We were to own the product trademark and to manufacture or arrange for supply of the product for commercial sales. Par was to be the sole distributor of the product. Both parties were to share commercialization expenses, including pre-marketing costs and promotion costs, on an equal basis. Operating profits from sales of the product were also to be shared on an equal basis. Under the agreement, we received an upfront fee of $5.0 million and a commitment from Par to fund all further development expenses. Development expenses incurred by us were to be partially funded by quarterly payments aggregating $28 million over the period of July 2004 through October 2005, of which up to $14 million was contingently refundable.

Revenue related to the receipt of the quarterly payments from Par was recognized based on actual costs incurred as the work was performed, limited to the minimum amounts expected to be received under the agreement and excluding amounts contingent on future events or that were contingently refundable, with the balance of cash received in excess of revenue recognized recorded as deferred revenue. The excess of the development costs incurred by us over the quarterly payments made by Par was to be funded subsequent to commercialization, by the distribution to us of Par's share of operating profits until the excess amount had been reimbursed. We did not record any amounts as revenue on a current basis that were dependent on achievement of future operating profits.

On August 3, 2005, we were notified by Par of its decision to terminate the Amoxicillin PULSYS collaboration agreement. Under certain circumstances, the termination clauses of the agreement may entitle Par to receive a share of net profits up to one-half of their $23.25 million funding of the development of certain Amoxicillin PULSYS products, should a product covered by the agreement be successfully commercialized. Accordingly, in the third quarter of 2005 we retained deferred revenue of $11.625 million related to the agreement, and we recognized revenue for the remaining balance of $2.4 million of previously deferred reimbursement revenue.

Termination of the Collaboration with GlaxoSmithKline

In July 2003, we entered into a license agreement with GlaxoSmithKline (GSK) pursuant to which we licensed patents and PULSYS technology to GSK for use with its Augmentin (amoxicillin/clavulanate combination) products and with limited other amoxicillin products. Under the agreement, GSK was responsible, at its cost and expense, to use commercially reasonable efforts for the clinical development, manufacture and sale of the licensed products. We received an initial non-refundable payment of $5 million from GSK upon signing of the agreement, and a $3 million payment upon achievement of the first milestone. Our receipt of further milestone payments, royalty payments and sales milestone payments under the agreement depended on the ability of GSK to develop and commercialize the products covered by the agreement and was subject to certain conditions and limitations.

The agreement could be terminated at any time by GSK upon relatively short notice. On October 15, 2004, we were notified that GSK would terminate the collaboration, effective December 15, 2004. As a result of the termination, we accelerated the recognition of the remaining deferred revenue of approximately $3.2 million related to the collaboration during the fourth quarter of 2004. The termination had no other effects on our financial position.

Collaboration with Par Pharmaceutical for Generic Clarithromycin

In September 2003, we entered into an agreement pursuant to which we licensed to Par Pharmaceutical the distribution and marketing rights to our generic formulation of Abbott's Biaxin XL (extended release clarithromycin). During the third quarter of 2004, we conducted bioequivalence studies on two revised formulations of the generic product, with both formulations failing to achieve bioequivalence. We concluded that due to the non-core nature of the product, the expense involved in the development of additional formulations, the continued redirection of our resources required to pursue the product, and the reduced market potential given the emergence of competing products, we would discontinue further development work on the product.

Sales and Marketing

We currently have a targeted and dedicated national contract sales force of approximately 75 sales representatives and seven Advancis district sales managers promoting Keflex 750 mg capsules to high-prescribing physicians across the U.S. We are also selling Keflex 250 mg capsules and 500 mg capsules; however, do not actively promote those Keflex strengths as their markets are dominated by generic equivalents. We are currently focusing our sales and marketing initiatives solely on the promotion of Keflex 750 mg capsules in an effort to maximize the impact from what we believe to be our greatest market opportunity. We also have a small marketing staff supporting our sales of the Keflex brand of cephalexin. The selling and marketing of Keflex 750mg capsules is a substantial financial commitment to our company. As a result, we may consider alternative commercialization strategies for our Keflex 750mg capsules in 2007 in an effort to reduce the financial resources required to market the product and/or to maximize the profit derived from the product.

Keflex is primarily sold directly to pharmaceutical wholesalers. In the pharmaceutical industry there are a limited number of major wholesalers responsible for the majority of sales. Product sales of Keflex to Cardinal Health Inc., McKesson Corporation, and AmerisourceBergen Corporation represented approximately 91 percent of our net revenue from Keflex in 2006.

In June 2006, we entered into marketing agreements with Innovex, the commercialization division of Quintiles Transnational Corporation, to provide us contract sales and marketing services for the promotion of Keflex 750 mg capsules. We received marketing approval from the FDA in May 2006 and launched Keflex 750 mg capsules in July 2006.

We believe our Keflex commercialization efforts could be effectively leveraged should we be successful in gaining marketing approval for Amoxicillin PULSYS. For both Keflex and Amoxicillin PULSYS, we expect to target high-volume prescribers with a community-based sales force. We believe developing our internal sales capability will enable us to sell and market Keflex and our proprietary PULSYS products in concentrated markets. Assuming we have sufficient financial and other resources, we expect to continue primarily using a contract sales organization directed by our internal managers to provide our commercialization capabilities, especially during the early stages of our sales force development.

We believe that a significant percentage of prescriptions for first-line, broad-spectrum antibiotics is written by high-volume prescribers who can be reached by a community-based sales force. Over time, and if we are successful in obtaining sufficient capital, we may expand our sales and marketing capabilities to provide even greater support of our target audience. We may also enter into agreements with other parties to capitalize on their sales and marketing capabilities in order to optimally market our products.

We currently manage the distribution of our Keflex products, including warehousing and shipping, through Integrated Commercialization Solutions, a division of AmerisourceBergen Corporation.

If we successfully develop and receive regulatory approval to market additional product candidates, we believe we will have to substantially expand our sales and marketing capabilities and/or enter into partnerships with other pharmaceutical companies to successfully commercialize our product candidates. We will need to successfully recruit additional sales and marketing personnel and build our sales and marketing infrastructure to successfully commercialize Amoxicillin PULSYS and any additional products or product candidates that we develop, acquire or license. Additional financial resources would be required to expand our current sales and marketing capabilities. Our future profitability will depend in part on our ability to develop additional sales and marketing capabilities to commercialize our future products to our target audiences.

Competition

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies, as well as smaller emerging companies. Our main competitors are:

- Large pharmaceutical companies, such as Pfizer, GlaxoSmithKline, Wyeth, Bristol-Myers Squibb, Merck, Johnson & Johnson, Roche, Schering-Plough, Novartis, sanofi-aventis, Abbott Laboratories, AstraZeneca, and Bayer, that may develop new drug compounds that render our drugs obsolete or noncompetitive.
- Smaller pharmaceutical and biotechnology companies and specialty pharmaceutical companies engaged in focused research and development of anti-infective drugs, such as Trimeris, Vertex, Adams Respiratory Therapeutics, Gilead Sciences, Cubist, Basilea, Replidyne, InterMune, Oscient, King, Advanced Life Sciences, and others.
- Drug delivery companies, such as Johnson & Johnson's Alza division, Biovail, DepoMed, Flamel Technologies, and SkyePharma, which may develop a dosing regimen that is more effective than pulsatile dosing.
- Generic drug companies, such as Teva, Ranbaxy, IVAX, Sandoz and Stada, which produce low-cost versions of antibiotics that may contain the same active pharmaceutical ingredients as our PULSYS product candidates.

There are many approved antibiotics available to treat bacterial conditions in the United States. Our product Keflex, and products that are in development, will compete with other available products based primarily on:

- efficacy
- safety
- tolerability
- acceptance by doctors
- patient compliance and acceptance
- patent protection
- convenience
- price
- insurance and other reimbursement coverage
- distribution

- marketing
- adaptability to various modes of dosing.

Our Keflex brand of cephalexin faces significant competition from generic distributors of cephalexin capsules and suspension. Currently, a significant portion of the prescriptions written for our Keflex 250 mg and 500 mg capsules are substituted at the pharmacy with generic versions of Keflex, supplied through leading generic drug manufacturers including Teva, Stada, IVAX, Ranbaxy, and others. In addition, our Keflex 750 mg capsules are not covered by patent protection and thus would be subject to similar competition from generic versions of Keflex 750 mg capsules if and when generic drug manufacturers decide to pursue the manufacture and marketing approvals required for a generic 750 mg strength cephalexin product.

In some instances, our novel products that utilize our PULSYS technology may compete against non-pulsatile drug products that share the same active ingredient, but are less convenient or require more cumbersome administration schedules. A number of these non-pulsatile drug products are available in generic form, which are usually substantially less expensive than the branded version. Companies such as Teva, Ranbaxy, IVAX, Sandoz and Stada, and others are major manufacturers and distributors of generic versions of antibiotics with whom we may compete in the future.

New developments, including the development of methods of preventing the incidence of disease, such as vaccines, occur rapidly in the pharmaceutical industry. These developments may render our product candidates or technologies obsolete or noncompetitive.

Many of our competitors possess greater financial, managerial and technical resources and have established reputations for successfully developing and marketing drugs, all of which put us at a competitive disadvantage. Our competitors may be able to apply their resources and capabilities to develop and commercialize products that have distinct, enhanced, or perceived advantages versus our products. The competitors may be in a position to devote greater resources in the sales, marketing, and distribution of these products and therefore considerably impact our ability to successfully commercialize our own products.

Manufacturing

We currently rely on third-party contract manufacturers to produce sufficient quantities of our product candidates for use in our preclinical studies and clinical trials, and to produce sufficient quantities of commercial supplies of our marketed products. We believe that our initial focus on the production of improved formulations of approved and marketed drugs will reduce the risk and time involved in the development of manufacturing capabilities because production of these drugs involves well-established and well-accepted manufacturing techniques and processes. We intend to continue to rely upon third-party contract manufacturers for production of our clinical and commercial supplies. The use of third-parties for these activities allows us to minimize our initial capital investment and reduce the risk that would be associated with the establishment of our own commercial manufacturing and distribution operations. With the possible transition to non-beta lactam products, we anticipate that our pilot facility could satisfy our drug production needs for clinical supplies through at least Phase II and, in some cases, through Phase III clinical trials.

In December 2004, we entered into a commercial supply agreement with Ceph International Corporation, a wholly owned subsidiary of Patheon's MOVA Pharmaceutical Corporation, to secure a long-term supply for our Keflex brand of products. This agreement provides for commercial supply of our Keflex product beyond the transitional period agreed to by Eli Lilly as part of our June 2004 acquisition.

In April 2005, we entered into agreements under which Stada Production Ireland Limited ("SPI"), previously known as the manufacturing division of Clonmel Healthcare Limited, a subsidiary of Stada Arzneimittel AG, will provide us with commercial supply of our Amoxicillin PULSYS products currently being evaluated by the FDA. SPI has capacity in place to cover current projected needs for an initial commercial phase, with additional capacity for growth. In addition to commercial supply, Advancis and SPI have also finalized an agreement for technology transfer, clinical/stability batches and commercial scale-up and validation, as well as an agreement covering Advancis-funded facility build-out and equipment additions to support the commercial manufacturing program.

In connection with our manufacturing activities, we generate hazardous waste. We are subject to federal and state regulation regarding the disposal of hazardous and potentially hazardous waste. We may incur costs to comply with such regulations now or in the future.

Patent and Intellectual Property Protection

Our success depends in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. We seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Further, all of our employees have executed agreements assigning to us all rights to any inventions and processes they develop while they are employed by us.

In addition, we intend to use license agreements to access external products and technologies, as well as to convey our own intellectual property to others. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. Protection of our intellectual property rights is subject to a number of risks.

We currently own 25 issued U.S. patents, 23 U.S. patent applications and 2 foreign patents. Our issued patents cover certain compositions and methods using pulsatile dosing. We also own 67 foreign-filed patent applications, which correspond to our U.S. patents and applications. We also own four International (PCT) patent applications, each of which International (PCT) patent applications we anticipate converting into several individually foreign-filed patent applications to further correspond to our U.S. patents and applications.

Government Regulation

We are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and promotion of drugs promulgated under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and by comparable agencies in foreign countries. FDA approval is required before any new drug can be marketed in the United States.

New Drug Application Process

The process required by the FDA before a new drug may be marketed in the United States generally involves:

- Completion of preclinical laboratory and animal testing.
- Submission of an investigational new drug application (IND) which must become effective before the commencement of clinical trials.
- Performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product's intended use.
- Submission to and approval by the FDA of a New Drug Application (NDA) which includes inspection of manufacturing facilities.

PRECLINICAL: Preclinical studies generally include laboratory evaluation of product chemistry, formulation and stability, as well as animal studies, to assess the safety and efficacy of the product. Preclinical trials also provide a basis for design of human clinical studies.

Human clinical trials are typically conducted in three sequential phases which may overlap:

PHASE I: During typical Phase I studies, the drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

PHASE II: During Phase II studies, the drug is introduced to patients that have the medical condition that the drug is intended to treat. Phase II studies are intended to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Phase II studies are sometimes combined with Phase I studies (referred to as Phase I/II studies) in certain

instances when safety issues and questions of absorption, metabolism, distribution and excretion are well-established.

PHASE III: When Phase II evaluations suggest that a dosage range of the product is effective and has an acceptable safety profile, Phase III trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population, often at geographically dispersed clinical study sites.

The drug sponsor, the FDA or the institutional review board at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a concern that the subjects are being exposed to an unacceptable health risk.

The results of product development, preclinical studies and human studies are submitted to the FDA as part of the NDA. The NDA also must contain extensive manufacturing information. The FDA may approve or disapprove the NDA if applicable FDA regulatory criteria are not satisfied or it may require additional data, including clinical data, to continue to evaluate the NDA.

As an alternate path to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act permits the filing 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 other words, the applicant can rely upon certain preclinical or clinical studies conducted for an approved product and only perform those additional studies or measurements that are needed to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. In our NDA submissions, we intend to rely, in part, on prior FDA approvals of the antibiotic ingredients used in our products and on data generated by other parties which help to demonstrate the safety and effectiveness of those ingredients. In the case of products that we may develop in conjunction with sponsors of previously approved products, we expect that we will have a specific right of reference to the data contained in the prior applications and submit a traditional NDA. In any case in which we do not have a specific right of reference from the sponsor of the previously approved product, we anticipate that we will submit Section 505(b)(2) NDAs All data necessary to satisfy the FDA of the safety and effectiveness of our own versions of these products will have to be generated by or for us and submitted to the FDA in support of our applications. These data are expected to include data establishing the safety and efficacy of the pulsatile dosage form and any other differences between the dosage form and the conditions for use of our products and the dosage form and conditions for use of the previously approved products.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted 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. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a paragraph iv certification. Absent a paragraph iv certification, the Section 505(b)(2) NDA will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) application also will 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. These procedures and limitations will not apply to the products in our development pipeline which contain active ingredients that are classified by FDA as antibiotics and that were the subject of marketing applications submitted to FDA prior to November 21, 1997. The only active ingredients which may be considered in future development projects which do not fall within this exempt antibiotic category are metronidazole, and fluoroquinolones such as ciprofloxacin. Of these, at the present time, we do not believe that the applicable limitations will have any effect on any potential future metronidazole development projects. With respect to products containing fluoroquinolones such as ciprofloxacin, in the absence of a licensing agreement, any application for approval that we submit to FDA may need to include statutorily-required certifications regarding our non-infringement of certain patents covering previously approved products, we may be required to notify the original NDA holder and patent

holder of those filings, and we may be subject to approval delays of up to 30-months, or longer, in the event that the patent holder brings suit against us for patent infringement within 45 days of such notifications.

In the case of antibiotic ingredients not previously approved in the combinations that we propose, it will also be necessary for us to satisfy the FDA's combination drug policy with data establishing that each active component contributes to the effectiveness of the combination and that the dosage of each component is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy. This policy typically requires very large clinical trials that test each antibiotic alone and in combination. In its review of our NDA submissions, the FDA will have broad discretion to require us to generate data on these matters. No assurance can be given that NDAs submitted for our products will receive FDA approval on a timely basis, or at all.

For all of the products that we have in development that contain antibiotic ingredients that were submitted to the FDA for approval prior to November 21, 1997, we will not, under current law, be able to submit to the FDA patent information covering those products. Therefore, once approved, the FDA's Orange Book, which lists patent information on drug products, will not include patent information on those products. As a consequence, potential competitors who submit 505(b)(2) or ANDA applications for generic versions of those products will not have to provide certifications regarding any of our patents that they may infringe or to provide us notice if they intend to market their products prior to expiration of those patents. Additionally, if we bring a patent infringement action against any such applicants, there will be no automatic 30-month stay of approval of those potentially infringing products. However, we would be entitled to pursue traditional patent-law procedures and remedies, such as preliminary and permanent injunctions. In the case of potential generic versions of any of our products that are not classified as exempt antibiotics, such as those containing only metronidazole or fluoroquinolone ingredients such as ciprofloxacin, we would be entitled to list our applicable patents in the Orange Book, potential competitors who submit 505(b)(2) or ANDA applications for generic version of those products would be subject to the certification and notice requirements, and there could be automatic 30-month stays of approval of the generic products while we pursue patent infringement actions against the applicants.

Under the Prescription Drug User Fee Act (PDUFA) generally, the submission of an NDA is subject to substantial application user fees, currently $896,200, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently $49,750 per product and $313,100 per establishment. These fees are typically increased annually. We believe that the first NDA submission for our pulsatile drug products may be eligible for a waiver of the application fee because of our status as a small business under the user fee statutes. In addition, the PDUFA statute has been subject to significant amendments in connection with its regular reauthorization. We are not in a position to predict whether and how the user fee requirements will be interpreted and applied to us and our products in the future.

Other Regulatory Constraints

In addition to the results of product development, preclinical animal studies and clinical human studies, an NDA also must contain extensive information on the chemistry, manufacturing and controls that relate to the planned routine production and testing of the drug. An NDA must also contain proposed prescribing information for the product, supported by available clinical and other testing data, describing how the product may properly be used. The FDA may approve, deny approval or grant conditional approval depending on whether it finds that information provided sufficiently addresses all issues regarding the manufacture and proposed use of the product candidate. Both prior to and subsequent to approval, the Federal Food, Drug, and Cosmetic Act and FDA regulations require that the manufacture and testing of any drug for investigational use or for commercial use in humans be manufactured in accordance with current Good Manufacturing Practice (cGMP). Failure to follow cGMP requirements, as well as other regulatory requirements, can subject a sponsor and its products to various sanctions, including civil and criminal penalties, injunctions against the distribution of products and seizure of violative products. cGMP requirements are complex, are not always clearly defined, and can evolve over time. We have used, and intend to continue to use, third-party firms that we believe are knowledgeable and qualified in compliance with cGMP requirements to manufacture and test our product candidates and, to the extent that we engage in these activities on our own behalf, intend to utilize cGMP-compliant procedures and controls. There can be no assurance, however, that we or our contractors will be and remain at all times in full compliance with all cGMP requirements. In addition, the FDA retains authority to object to promotional activities engaged in by the applicant, including

promotional activities that exceed the scope of approved prescribing information. Under certain circumstances, the FDA may also impose post-marketing testing requirements and may propose to withdraw or suspend approval of products based on new information about their safety and effectiveness for their approved uses.

Foreign Regulatory Approval

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

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the application and assessment report, each member state must decide whether to recognize approval. We plan to choose the European regulatory filing procedure that we believe will allow us to obtain regulatory approvals quickly. However, the chosen regulatory strategy may not secure regulatory approvals or approvals of the chosen product indications. In addition, these approvals, if obtained, may take longer than anticipated.

Obtaining foreign regulatory approvals would require additional financial resources and in the event we choose to seek those approvals, we would need to raise additional capital. We cannot assure you that any of our product candidates will prove to be safe or effective, will receive regulatory approvals, or will be successfully commercialized.

Employees

As of February 28, 2007, we had 76 employees, 9 of whom are senior management, 39 are in supervisory positions and 28 are non-management. Of the 76 employees, 38 perform scientific and research activities and 21 hold advanced degrees.

Item 1A. ***Risk Factors***

There are a number of important factors that could cause our actual results to differ materially from those that are indicated by forward-looking statements. Those factors include, without limitation, those listed below and elsewhere herein.

Risks Related to our Business

We have a history of losses, we expect to incur losses for the foreseeable future and we may never become profitable.

From the date we began operations in January 2000 through December 31, 2006, we have incurred operating losses of approximately $154.8 million, including operating losses of approximately $43.4 million for the fiscal year ended December 31, 2006, $34.0 million for the fiscal year ended December 31, 2005 and $34.7 million for the fiscal year ended December 31, 2004. Our losses to date have resulted principally from research and development costs related to the development of our product candidates, the purchase of equipment and establishment of our facilities and general and administrative costs related to our operations.

We expect to incur substantial losses in 2007 and for the foreseeable future thereafter. Among other things, in 2007 we expect to incur significant expenses in anticipation of commercialization of our Amoxicillin PULSYS product candidate. We have postponed further development of our Keflex PULSYS product candidate and our pediatric PULSYS product candidate in 2007 in order to reduce our expenses. We may also incur losses in connection with the continued sales and marketing of our 750 mg Keflex product that was approved for marketing by the FDA in May 2006. In addition, we expect to incur additional expenses as a result of other research and development costs and regulatory compliance activities.

Our chances for achieving profitability depend on numerous factors, including success in:

- obtaining additional financing;
- obtaining FDA approval for our Amoxicillin PULSYS product candidate and, if approved, successfully commercializing this product;
- increasing sales of our 750 mg Keflex product; and
- successfully developing, gaining FDA approval for and commercializing other product candidates.

We may never become profitable.

If we are unable to raise additional capital in the near term, we may not be able to continue to operate as a going concern.

Revenues we currently generate from our 750 mg Keflex product and other Keflex product sales are insufficient to cover our expenses. Our existing capital resources and revenue from expected product sales will not be sufficient for us to maintain our current operations for the next 12 months, and we will require additional capital to fund our operations beyond the second quarter of 2007. Our requirements for additional capital are substantial. We currently have no committed source of capital, although we are evaluating a number of alternatives. We cannot assure you that financing will be available to us or, if available, that it will be on favorable terms. To the extent we raise additional capital through the sale of equity securities, the issuance of those securities could result in substantial dilution to our existing stockholders. In addition, if we obtain debt financing, we may be required to pledge all or a significant portion of our assets to secure such debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness and we may become subject to financial covenants and other terms that restrict the manner in which we can operate our business. If we are unable to raise additional capital, we may need to sell assets, pursue other strategic alternatives and/or curtail significantly our development and commercialization activities, and we may be unable to continue as a going concern.

Even if we are able to raise capital in the near term, the amount of funds we are able to raise may not be sufficient to cover our anticipated expenses for the next twelve months and allow us to commercially launch our Amoxicillin PULSYS product should it receive FDA approval. We anticipate that we may need to raise capital on more than one occasion to meet our anticipated expenses for the next twelve months and commercially launch Amoxicillin PULSYS if it is approved by the FDA. We further anticipate that we will also need to raise additional capital in the future to allow us to continue to develop Keflex PULSYS and our other products under development.

If we are unable to increase sales of our 750 mg Keflex product, our liquidity will be further adversely affected.

We launched our 750 mg Keflex product in July 2006. While we have invested considerable resources in the launch of this product, to date, sales have not met our expectations. We had previously anticipated that this product would generate revenues in excess of related expenses and would contribute additional cash flow to help fund our other operations by the end of 2007. We cannot assure you that this will occur, as this product may not gain sufficient market acceptance among physicians, the medical community and patients. The extent to which this product is accepted by physicians is dependent upon a number of factors, including the recognition of the potential advantages, despite higher cost, over alternative generic dosage strengths of cephalexin and the effectiveness of our marketing and distribution capabilities. In addition, this product faces significant competition from other dosage strengths of cephalexin manufactured by generic pharmaceutical companies, as well as from other dosage strengths of Keflex marketed by us. Although there is no current 750 mg dosage strength of generic cephalexin, the product is not protected by patents and we expect to have a limited window of opportunity to market this product, should generic pharmaceutical manufacturers choose to compete with us. If our 750 mg Keflex product does not achieve greater market acceptance, our liquidity will further suffer. Even if sales of this product increase in the short-term, we expect that the amount of revenues from this product could decline significantly within a few years due to competition from generic formulations of the product.

Assuming we are able to obtain additional capital, our nearer term success will depend in large part on our receiving FDA approval of our Amoxicillin PULSYS product candidate, and we cannot assure you that the FDA will approve this product or, if approved, that it will be approved on a timely basis.

Assuming we are able to raise additional capital in the near term, our nearer term success will depend on our obtaining FDA approval for our Amoxicillin PULSYS product candidate. We conducted our first Phase III clinical trial for adult pharyngitis in the 2005, using a 7-day duration of therapy. This study failed to achieve its desired microbiological and clinical end points. On August 10, 2006, we publicly reported results of a re-designed Phase III clinical trial for Amoxicillin PULSYS using a 10-day treatment period. On December 14, 2006, we submitted a 505(b)(2) New Drug Application to the FDA for our adult and adolescent Amoxicillin PULSYS product, based upon the data from our successfully concluded Phase III trial. On February 12, 2007, we received a "refusal to file" letter from the FDA, requesting additional information on our planned commercial manufacturing processes. In its letter, the FDA indicated that our application was not sufficiently complete in that it did not include a proposed commercial batch record or a detailed commercial process description with process parameters and in-process controls. We conducted a meeting with the FDA regarding our Amoxicillin PULSYS NDA on February 26, 2007. In that meeting, we reached agreement with the FDA on the additional information that is required for our NDA filing to be accepted. We resubmitted a 505(b)(2)NDA to the FDA for our adult and adolescent amoxicillin product on March 23, 2007. In accordance with FDA guidelines, the FDA has 60 days to preliminarily review the NDA submission and assess whether the application is acceptable for filing and substantive review. We expect to receive a filing decision in May 2007, and if accepted for filing, to receive a FDA target action date in January 2008. We cannot assure you that the FDA will accept our revised NDA for filing or, if the filing is accepted, that the FDA will approve our NDA or, if it approves the NDA, that it will do so on a timely basis. Even if our Amoxicillin PULSYS product candidate is approved by the FDA, the earliest we believe we could launch Amoxicillin PULSYS would be in early 2008.

Among the many risks we face in obtaining FDA approval of our Amoxicillin PULSYS product is the risk that the FDA requires us to conduct additional large-scale clinical trials, which may delay or prevent commercialization of Amoxicillin PULSYS. Historically, the FDA and foreign regulatory authorities have not required placebo-controlled clinical trials for approval of the pharyngitis/tonsillitis indication but instead have relied on non-inferiority studies. In a non-inferiority study, a drug candidate is compared with an approved antibiotic treatment and it must be shown that the product candidate is not less effective than the approved treatment. All efficacy studies upon which our NDA is based were designed as non-inferiority studies after consultation with the FDA. However, more recently the FDA has required placebo-controlled trials for other indications. We cannot assure you that the FDA will not require placebo-controlled trials, or other trials involving comparator antibiotics, to demonstrate the superiority of Amoxicillin PULSYS to placebo before considering the approval of Amoxicillin PULSYS. Conducting placebo-controlled trials for antibiotics can be time consuming and expensive and can be difficult to complete. Institutional review boards may not grant approval for placebo-controlled trials because of ethical concerns about denying some participating patients access to any antibiotic therapy during the course of the trial. It may be difficult to enroll patients in placebo-controlled trials even if institutional review board approval is obtained because certain patients would receive no therapy. These factors could delay for several years or ultimately prevent commercialization of Amoxicillin PULSYS for any indications for which the FDA requires placebo-controlled trials.

Our PULSYS technology is based on a finding that could ultimately prove to be incorrect, or could have limited applicability.

Our PULSYS product candidates are based on our finding that bacteria exposed to antibiotics in front-loaded, rapid sequential bursts are eliminated more efficiently and effectively than those exposed to presently available treatment regimens. Ultimately, our finding may be incorrect, in which case our pulsatile drugs would not differ substantially from competing drugs and may be inferior to them. If these products are substantially identical or inferior to products already available, the market for our pulsatile drugs will be reduced or eliminated.

Even if pulsatile dosing is more effective than traditional dosing, we may be unable to apply this finding successfully to a substantial number of products in the anti-infective market. Our preliminary studies indicate that pulsatile dosing may not provide superior performance for all types of antibiotics. Additionally, we have not

conducted any studies with anti-viral or anti-fungal medications. If we cannot apply our technology to a wide variety of antibiotics or other anti-infectives, our potential market will be substantially reduced.

Our PULSYS delivery technology may not be effective, which would prevent us from commercializing products that are more effective than those of our competitors.

Even if we are correct that pulsatile dosing is more effective than traditional dosing of antibiotics, our PULSYS delivery technology must be effective in humans such that the pulsatile administration of drugs are at levels that prove effective in curing infections. If our PULSYS delivery technology is not effective in delivering rapid bursts of antibiotics, or is unable to do so at an appropriate concentration and we are not able to create an alternative delivery method for pulsatile dosing that proves to be effective, we will be unable to capitalize on any advantage of our discovery. Should this occur, our pulsatile product candidates may not be more effective than the products of our competitors, which may decrease or eliminate market acceptance of our products.

If a competitor produces and commercializes an antibiotic that is superior to our PULSYS antibiotics, the market for our potential products would be reduced or eliminated.

We have devoted a substantial amount of our research efforts and capital to the development of pulsatile antibiotics. Competitors are developing or have developed new drugs that may compete with our pulsatile antibiotics. For example, sanofi-aventis recently launched Ketek, a drug that belongs to a new class of antibiotics known as ketolides. This antibiotic may compete against our pulsatile antibiotics in the treatment of upper respiratory tract infections. A number of pharmaceutical companies are also developing new classes of compounds, such as oxazolidinones, that may also compete against our pulsatile antibiotics. In addition, other companies are developing technologies to enhance the efficacy of antibiotics by adding new chemical entities that inhibit bacterial metabolic function. If a competitor produces and commercializes an antibiotic or method of delivery of antibiotics that provides superior safety, effectiveness or other significant advantages over our pulsatile antibiotics, the value of our pulsatile drugs would be substantially reduced. As a result, we would need to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. In the event we are unable to establish new product targets, we will be unable to generate sources of revenue.

We have not conducted an extensive third party patent infringement, invalidity and enforceability investigation on pulsatile dosing and our PULSYS technology, and we are aware of at least one issued patent covering pulsatile delivery.

Our patents, prior art and infringement investigations were primarily conducted by our senior management and other employees. Although our patent counsel has consulted with management in connection with management's intellectual property investigations, our patent counsel has not undertaken an extensive independent analysis to determine whether our pulsatile technology infringes upon any issued patents or whether our issued patents or patent applications covering pulsatile dosing could be invalidated or rendered unenforceable for any reason. We are aware of one issued patent owned by a third party that covers certain aspects of delivering drugs by use of two delayed release pulses. The patent covers a drug delivery system employing two delayed release pulses using two polymers. The claims made by this patent could be argued to cover certain aspects of our technology. However, we believe that we will be able to manufacture and market formulations of our pulsatile products without infringing any valid claims under this patent. Any reformulation of our products, if required, could be costly and time-consuming and may not be possible. We cannot assure you that a claim will not be asserted by such patent holder or any other holder of an issued patent that any of our products infringe their patent or that our patents are invalid or unenforceable. We may be exposed to future litigation by third parties based on claims that our products or activities infringe the intellectual property rights of others. We cannot assure you that, in the event of litigation, any claims would be resolved in our favor. Any litigation or claims against us, whether or not valid, may result in substantial costs, could place a significant strain on our financial resources, divert the attention of management and harm our reputation. In addition, intellectual property litigation or claims could result in substantial damages and force us to do one or more of the following:

- cease selling, incorporating or using any of our products that incorporate the challenged intellectual property;

- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our products, which would be costly and time-consuming and may not be possible.

We have not sought patent protection for certain aspects of the technology used in our PULSYS product candidates.

We have not filed for patent protection with respect to all of our specific formulations, materials (including inactive ingredients) or manufacturing process approaches that are incorporated in our PULSYS product candidates, and we may not seek such patent coverage in the future. In producing our PULSYS products, we expect to use general formulation techniques used in the industry that would be modified by us and which would, therefore, include know-how and trade secrets that we have developed. We cannot be certain that a patent would issue to cover such intellectual property, and currently, we would prefer to keep such techniques and know-how as our trade secrets. In the event a competitor is able to develop technology substantially similar to ours and patent that approach, we may be blocked from using certain of our formulations or manufacturing process approaches, which could limit our ability to develop and commercialize products.

If we are unable to develop and successfully commercialize our PULSYS product candidates, we may never achieve profitability.

We have not commercialized any PULSYS products or recognized any revenue from PULSYS product sales. With the exception of our Amoxicillin PULSYS product, all of our pulsatile drugs are in early stages of development with a total of only four pulsatile product candidates having been tested in Phase I/II clinical trials to date. Our Amoxicillin PULSYS product has successfully completed a Phase III clinical trial, however, we must obtain regulatory approval for our products before we are able to commercialize these products and generate revenue from their sales. We expect that we must conduct significant additional research and development activities on our other PULSYS product candidates and successfully complete preclinical, Phase I, Phase I/II or Phase II, and Phase III clinical trials before we will be able to receive final regulatory approval to commercialize these pulsatile products. Even if we succeed in developing and commercializing one or more of our PULSYS products, we may never generate sufficient or sustainable revenue to enable us to be profitable.

If clinical trials for our products are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines.

We must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for use in humans before we can obtain regulatory approvals for their commercial sale. In addition, we will also need to demonstrate through clinical trials any claims we may wish to make that our product candidates are comparable or superior to existing products. For drug products which are expected to contain active ingredients in fixed combinations that have not been previously approved by the FDA, we may also need to conduct clinical studies in order to establish the contribution of each active component to the effectiveness of the combination in an appropriately identified patient population.

Conducting clinical trials is a lengthy, time-consuming and expensive process. With the exception of our Amoxicillin PULSYS product candidate that has completed Phase III clinical trials, we have not completed preclinical studies and initial clinical trials (Phase I, Phase I/II or Phase II) to extrapolate proper dosage for our product candidates for Phase III clinical efficacy trials in humans. In the event we incorrectly identify a dosage as appropriate for human clinical trials, any results we receive from such trials may not properly reflect the optimal efficacy or safety of our products and may not support approval in the absence of additional clinical trials using a different dosage.

The commencement and rate of completion of clinical trials for our products may be delayed by many factors, including:

- lack of efficacy during the clinical trials;
- unforeseen safety issues;

- slower than expected rate of patient recruitment; or
- government or regulatory delays.

The results from preclinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. Although a new product may show promising results in preclinical and initial clinical trials, it may subsequently prove unfeasible or impossible to generate sufficient safety and efficacy data to obtain necessary regulatory approval. Data obtained from preclinical and clinical studies are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may encounter regulatory delays or rejections as a result of many factors, including results that do not support our claims, perceived defects in the design of clinical trials and changes in regulatory policy during the period of product development. Our business, financial condition and results of operations may be materially adversely affected by any delays in, or termination of, our clinical trials or a determination by the FDA that the results of our trials are inadequate to justify regulatory approval.

Even if Amoxicillin PULSYS or any of our other PULSYS products are approved for commercial sale, we will not be successful if these products are not accepted by the market.

Even if we obtain regulatory approval to market Amoxicillin PULSYS or any of our other PULSYS product candidates, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any pharmaceutical product that we develop will depend on a number of factors, including:

- demonstration of clinical efficacy and safety;
- cost-effectiveness;
- potential advantages over alternative therapies;
- reimbursement policies of government and third-party payors; and
- effectiveness of our marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners.

Our products will compete with a number of products manufactured and marketed by major pharmaceutical companies, biotechnology companies and manufacturers of generic drugs. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept and use any product candidates that we or our collaborative partners develop. To the extent current antibiotics already successfully treat certain infections, physicians may not be inclined to prescribe our pulsatile drugs for the same indications. If our products do not achieve significant market acceptance, we will not be able to generate significant revenues or become profitable.

We have limited sales, marketing, and distribution capabilities, and currently depend in large part on a third party contract sales force for the marketing of our Keflex 750 mg product. If we fail to develop our own sales, marketing and distribution capabilities or fail to enter into arrangements with third parties, we will not be able to successfully commercialize our products.

We have limited sales, marketing, and distribution capabilities. We currently rely in large part on a third party contract sales force provided to us by Innovex, the commercialization division of Quintiles Transnational Corporation, for sales and marketing services relating to our Keflex 750 mg product. In the event we receive FDA approval for our Amoxicillin PULSYS product candidate or any other product candidates, we will need to considerably expand our commercial capabilities or make arrangements with third parties to perform these services for us. In order to market any of our product candidates directly, we must considerably expand our commercial infrastructure, including distribution, marketing and sales personnel. The expansion or contracting of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts. To the extent that we enter into sales and marketing arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be

successful. If we fail to expand sales, marketing and distribution capabilities, or fail to enter into arrangements with third parties, we will experience delays in product sales and incur increased costs.

We rely upon a limited number of pharmaceutical wholesalers and distributors, which could impact our ability to sell our Keflex products or Amoxicillin PULSYS.

We rely largely upon specialty pharmaceutical distributors and wholesalers to deliver Keflex to end users, including physicians, hospitals, and pharmacies. Product sales to the three major pharmaceutical wholesalers, Cardinal Health Inc., McKesson Corporation and AmerisourceBergen Corporation, represented approximately 91% of our net revenue from Keflex in 2006. There can be no assurance that our distributors and wholesalers will adequately fulfill the market demand for Keflex or, if approved for commercial sale, Amoxicillin PULSYS. Given the high concentration of sales to certain pharmaceutical distributors and wholesalers, we could experience a significant loss if one of our top customers were to declare bankruptcy or otherwise become unable to pay its obligations to us.

The potential success of our products and product candidates, including our 750 mg Keflex product and, if approved for marketing by the FDA, Amoxicillin PULSYS, will be dependent upon successfully pricing the products in the marketplace.

While we believe that physicians make antibiotic prescribing decisions based primarily on efficacy, safety, and compliance, we also believe that, when deciding whether to prescribe a modified-release drug or its immediate release generic analog, physicians also weigh patient co-pay and patient preferences. As a result, we believe that price will be an important driver of the adoption of our products and product candidates. In addition, we believe it will be important to carefully manage against resistance from payor organizations by pricing our products in such a way as to minimize the incremental payor cost burden relative to generic analogs.

Generic pricing plans, such as that being implemented by Wal-Mart, may affect the market for our products.

In September 2006, Wal-Mart announced plans to offer certain generic drugs at $4 per prescription. Amoxicillin and cephalexin are on the list of drugs that Wal-Mart intends to provide at $4 per prescription. Wal-Mart has significant market presence. As a result, there can be no assurance that Wal-Mart's generic pricing plan, and/or similar plans adopted by others, will not have a material adverse effect on the market for our products.

Our products are subject to therapeutic equivalent substitution, Medicaid reimbursement and price reporting.

The cost of pharmaceutical products continues to be a subject of investigation and action by governmental agencies, legislative bodies and private organizations in the U.S. and other countries. In the U.S., most states have enacted legislation requiring or permitting a dispensing pharmacist to substitute a generic equivalent to the prescribed drug. Federal legislation requires pharmaceutical manufacturers to pay to state Medicaid agencies prescribed rebates on drugs to enable them to be eligible for reimbursement under Medicaid programs. Federal and state governments continue to pursue efforts to reduce spending in Medicaid programs, including imposing restrictions on amounts agencies will reimburse for certain products. In addition, some states are seeking rebates in excess of the amounts required by federal law, and there are federal legislative proposals to expand current Medicaid rebates. We also must give discounts or rebates on purchases or reimbursements of our products by certain other federal and state agencies and programs. Our ability to earn sufficient returns on our products will depend, in part, on the availability of reimbursements from third party payers, such as health insurers, governmental health administration authorities and other organizations and the amount of rebates payable under Medicaid programs.

We are dependent on our contract manufacturers and suppliers to provide us with active pharmaceutical ingredients and finished products.

We do not maintain commercial scale manufacturing facilities. Our Keflex products are manufactured for us by Ceph International Corporation (Ceph), a wholly-owned subsidiary of Patheon's MOVA Pharmaceutical

Corporation. If approved by the FDA for commercial sale, Amoxicillin PULSYS is expected to be manufactured for us by Stada Production Ireland Limited (SPI), previously known as the manufacturing division of Clonmel Healthcare Limited, a subsidiary of STADA Arzneimittel AG, pursuant to a contract manufacturing arrangement we have entered into with them.

Although we believe that the active pharmaceutical ingredients and finished Keflex and Amoxicillin products could be potentially obtained from several suppliers, our applications for regulatory approval currently authorize only Ceph as our source for Keflex, and SPI is identified as our only source for amoxicillin in our Amoxicillin PULSYS NDA. In the event that Ceph and/or SPI is unable to supply the products to us in sufficient quantities on a timely basis or at a commercially reasonable price, or in the event either of them breaches their agreement with us, or if Ceph and/or SPI loses its regulatory status as an acceptable source, we would need to locate another source. A change to a supplier not previously approved or an alteration in the procedures or product provided to us by an approved supplier may require formal approval by the FDA before the product could be sold and could result in significant disruption to our business. These factors could limit our ability to sell Keflex and/or Amoxicillin PULSYS and could materially adversely affect our business, financial condition and results of operations.

In addition, we obtain active pharmaceutical ingredients (APIs) and finished products from certain specialized manufacturers for use in clinical studies. Although the antibiotics and finished products we use in our clinical studies may generally be obtained from several suppliers, the loss of a supplier could result in delays in conducting or completing our clinical trials and could delay our ability to commercialize products.

Our ability to conduct clinical trials will be impaired if we fail to qualify our clinical supply manufacturing facility and we are unable to maintain relationships with current clinical supply manufacturers or enter into relationships with new manufacturers.

We currently rely on several contractors to manufacture product samples for our clinical studies. In the fourth quarter of 2003, we completed construction of a manufacturing facility in Germantown, Maryland for production of clinical supplies sufficient for use through our Phase II and, in some cases, Phase III clinical trials. We currently have no plans to qualify the facility.

We intend to rely on third parties to manufacture products that we intend to sell through our own commercialization and sales efforts. We believe that there are a variety of manufacturers that we may retain to produce these products. However, once we retain a manufacturing source, if we are unable to maintain our relationship with such manufacturer, qualifying a new manufacturing source will be time consuming and expensive, and may cause delays in the development of our products.

Clinical trials for our product candidates may be delayed due to our dependence on third parties for the conduct of such trials.

We have limited experience in conducting and managing clinical trials. We rely, and will continue to rely, on third parties, including contract research organizations and outside consultants, to assist us in managing and monitoring clinical trials. Our reliance on these third parties may result in delays in completion of, or the failure to complete, these trials if they fail to perform their obligations under our agreements with them.

Our success may depend on our ability to successfully attract and retain collaborative partners.

For certain product candidates, we may enter into collaborative arrangements with third parties. Collaborations may be necessary in order for us to:

- fund our research and development activities;
- fund manufacturing by third parties;
- seek and obtain regulatory approvals; and
- successfully commercialize our product candidates.

We cannot assure you that we will be able to enter into collaborative agreements with partners on terms favorable to us, or at all, and any future agreement may expose us to risks that our partner might fail to fulfill its obligations and delay commercialization of our products. We also could become involved in disputes with partners, which could lead to delays in or terminations of our development and commercialization programs and time consuming and expensive litigation or arbitration. Our inability to enter into additional collaborative arrangements with other partners, or our failure to maintain such arrangements, may limit the number of product candidates we can develop and ultimately, decrease our sources of any future revenues. For a discussion of certain collaboration arrangements to which we were previously a party and which have been terminated, see the information under the caption "Collaboration Agreements" in Item 1 above.

If we cannot enter into new licensing arrangements or otherwise gain access to products, our ability to develop a diverse product portfolio could be limited.

A component of our business strategy may involve in-licensing or acquiring drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories that may be marketed and developed or improved upon using our novel technologies. Competition for promising compounds can be intense and currently we have not entered into any arrangement to license or acquire any drugs from other companies. If we are not able to identify licensing or acquisition opportunities or enter into arrangements on acceptable terms, we may be unable to develop a diverse portfolio of products. Any product candidate that we acquire may require significant additional research and development efforts prior to seeking regulatory approval and commercial sale, including extensive preclinical and/or clinical testing. All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe, non-toxic and effective or approved by regulatory authorities. In addition, we cannot assure you that any approved products that we develop or acquire will be: manufactured or produced economically; successfully commercialized; widely accepted in the marketplace or that we will be able to recover our significant expenditures in connection with the development or acquisition of such products. In addition, proposing, negotiating and implementing an economically viable acquisition is a lengthy and complex process. Other companies, including those with substantially greater financial, sales and marketing resources, may compete with us for the acquisition of product candidates and approved products. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all. In addition, if we acquire product candidates from third parties, we may be dependent on third parties to supply such products to us for sale. We could be materially adversely affected by the failure or inability of such suppliers to meet performance, reliability and quality standards.

We could be forced to pay substantial damage awards if product liability claims that may be brought against us are successful.

The use of any of our product candidates in clinical trials, and the sale of any approved products, may expose us to liability claims and financial losses resulting from the use or sale of our products. We have obtained limited product liability insurance coverage for our clinical trials, which we believe is adequate to cover our present activities. However, such insurance may not be adequate to cover any claims made against us. In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses.

Our executive officers and other key personnel are critical to our business and our future success depends on our ability to retain them.

We are highly dependent on the principal members of our scientific and management teams, especially Edward M. Rudnic, our president and chief executive officer. In order to pursue our product development, marketing and commercialization plans, we may need to hire additional personnel with experience in clinical testing, government regulation, manufacturing, marketing and business development. We may not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. We are not aware of any present intention of any of our key personnel to leave our company or to retire. However, although we have employment agreements with our executive officers, these employees may terminate their services upon 90 days advance notice. The loss of

any of our key personnel, or the inability to attract and retain qualified personnel, may significantly delay or prevent the achievement of our research, development or business objectives and could materially adversely affect our business, financial condition and results of operations. Although we maintain key man life insurance on Dr. Rudnic, such insurance may not be sufficient to cover the costs of the loss of his services and the expense of recruiting and hiring a new president and chief executive officer.

Risks Related to our Industry

Any inability to protect our intellectual property could harm our competitive position.

Our success will depend in part on our ability to obtain patents and maintain adequate protection of other intellectual property for our technologies and products in the U.S. and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate our competitive advantage. Further, the laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the U.S., and we may encounter significant problems in protecting our proprietary rights in these foreign countries.

The patent positions of pharmaceutical and biotechnology companies, including our patent positions, involve complex legal and factual questions and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that we cover our proprietary technologies with valid and enforceable patents or we effectively maintain such proprietary technologies as trade secrets. We will apply for patents covering both our technologies and product candidates as we deem appropriate. We may fail to apply for patents on important technologies or products in a timely fashion, or at all, and in any event, the applications we do file may be challenged and may not result in issued patents. Any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. In addition, if challenged, our patents may be declared invalid. Even if valid, our patents may fail to provide us with any competitive advantages.

We rely upon trade secrets protection for our confidential and proprietary information. We have taken measures to protect our proprietary information; however, these measures may not provide adequate protection. We seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose our proprietary information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

If we do not compete successfully in the development and commercialization of products and keep pace with rapid technological change, we will be unable to capture and sustain a meaningful market position.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. While we are not aware of any company using rapid bursts of antibiotics as a treatment method, there are numerous companies actively engaged in the research and development of anti-infectives.

Our main competitors are:

- Large pharmaceutical companies, such as Pfizer, GlaxoSmithKline, Wyeth, Bristol-Myers Squibb, Merck, Johnson & Johnson, Roche, Schering-Plough, Novartis, sanofi-aventis, Abbott Laboratories, AstraZeneca, and Bayer, that may develop new drug compounds that render our drugs obsolete or noncompetitive.
- Smaller pharmaceutical and biotechnology companies and specialty pharmaceutical companies engaged in focused research and development of anti-infective drugs, such as Trimeris, Vertex, Adams Respiratory Therapeutics, Gilead Sciences, Cubist, Basilea, Replidyne, InterMune, Oscient, King, Advanced Life Sciences, and others.

- Drug delivery companies, such as Johnson & Johnson's Alza division, Biovail, DepoMed, Flamel Technologies, and SkyePharma, which may develop a dosing regimen that is more effective than pulsatile dosing.
- Generic drug companies, such as Teva, Ranbaxy, IVAX, Sandoz and Stada, which produce low-cost versions of antibiotics that may contain the same active pharmaceutical ingredients as our PULSYS product candidates.

Many of these competitors, either alone or together with their collaborative partners, have substantially greater financial resources and larger research and development staffs than we do. In addition, many of these competitors, either alone or together with their collaborative partners, have significantly greater experience than we do in:

- developing products;
- undertaking preclinical testing and human clinical trials;
- obtaining approvals of products from the FDA and other regulatory agencies; and
- manufacturing and marketing products.

Developments by others may render our product candidates or technologies obsolete or noncompetitive. We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions, and for licenses of products or technology. These competitors, either alone or with their collaborative partners, may succeed in developing technologies or products that are more effective than ours.

If we experience delays in obtaining regulatory approvals, or are unable to obtain or maintain regulatory approvals, we may be unable to commercialize any products.

Our product candidates are subject to extensive and rigorous domestic government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record- keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our products are marketed abroad, they will also be subject to extensive regulation by foreign governments. None of our PULSYS product candidates has been approved for sale in the U.S. or any foreign market. The regulatory review and approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. The actual time required for satisfaction of FDA pre-market approval requirements may vary substantially based upon the type, complexity and novelty of the product or the medical condition it is intended to treat. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon a manufacturer's activities. Delays in obtaining regulatory approvals may:

- adversely affect the commercialization of any drugs that we or our collaborative partners develop;
- impose costly procedures on us or our collaborative partners;
- diminish any competitive advantages that we or our collaborative partners may attain; and
- adversely affect our receipt of revenues or royalties.

Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval.

Any required approvals, once obtained, may be withdrawn. Further, if we fail to comply with applicable FDA and other regulatory requirements at any stage during the regulatory process, we may encounter difficulties including:

- delays in clinical trials or commercialization;
- product recalls or seizures;
- suspension of production and/or distribution;

- withdrawals of previously approved marketing applications; and
- fines, civil penalties and criminal prosecutions.

We may rely on future collaborative partners to file investigational new drug applications and generally direct the regulatory approval process for some of our products. These collaborative partners may not be able to conduct clinical testing or obtain necessary approvals from the FDA or other regulatory authorities for any product candidates. If we fail to obtain required governmental approvals, we or our collaborative partners will experience delays in, or be precluded from, marketing products developed through our research.

We and our contract manufacturers also are required to comply with applicable FDA good manufacturing practice regulations. Good manufacturing practice regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in commercial manufacturing of our products. We or our contract manufacturers may not be able to comply with the applicable good manufacturing practice requirements and other FDA regulatory requirements. If we or our contract manufacturers fail to comply, we could be subject to fines or other sanctions, or be precluded from marketing our products.

The manufacture and storage of pharmaceutical and chemical products is subject to environmental regulation and risk.

Because of the chemical ingredients of pharmaceutical products and the nature of their manufacturing process, the pharmaceutical industry is subject to extensive environmental regulation and the risk of incurring liability for damages or the costs of remedying environmental problems. We use a number of chemicals and drug substances that can be toxic to humans. These chemicals include acids, solvents and other reagents used in the normal course of our chemical and pharmaceutical analysis, and other materials, such as polymers, inactive ingredients and drug substances, used in the research, development and manufacture of drug products. If we fail to comply with environmental regulations to use, discharge or dispose of hazardous materials appropriately or otherwise to comply with the conditions attached to our operating licenses, the licenses could be revoked and we could be subject to criminal sanctions and/or substantial liability or could be required to suspend or modify our operations.

Environmental laws and regulations can require us to undertake or pay for investigation, clean-up and monitoring of environmental contamination identified at properties that we currently own or operate or that we formerly owned or operated. Further, they can require us to undertake or pay for such actions at offsite locations where we may have sent hazardous substances for disposal. These obligations are often imposed without regard to fault. In the event we are found to have violated environmental laws or regulations, our reputation will be harmed and we may incur substantial monetary liabilities. We currently have insurance coverage that we believe is adequate to cover our present activities. However, this insurance may not be available or adequate to cover any losses arising from contamination or injury resulting from our use of hazardous substances.

Market acceptance of our products will be limited if users of our products are unable to obtain adequate reimbursement from third-party payors.

The commercial success of our products and product candidates will depend in part on the availability of reimbursement from third-party payors, including government health administrators, managed care providers and private health insurers. We cannot assure you that third-party payors will consider our products cost-effective or provide reimbursement in whole or in part for their use.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors may conclude that our products are less safe, effective or cost-effective than existing products. Therefore, third-party payors may not approve our products for reimbursement.

If third-party payors do not approve our products for reimbursement or fail to reimburse them adequately, sales will suffer as some physicians or their patients will opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third-party payors make reimbursement available, reimbursement levels may not be sufficient for us to realize an appropriate return on our investment in product development.

Moreover, the trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our products. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory agencies adopt these proposals, they could materially adversely affect our business, financial condition and results of operations.

Potential regulatory changes and the billing and reimbursement process applicable to underlying conditions may cause price erosion and reduce sales revenue for our products and our products may not be accepted by health care providers.

Government and private healthcare programs currently are under financial stress due to overall medical cost increases. Federal and state governments are taking steps to ease the burden on healthcare programs in ways that could affect the pricing of pharmaceuticals. Any such federal and state laws and regulations can have a negative impact on the pricing of prescription drugs, including Medicare, Medicaid, pharmaceutical importation laws and other laws and regulations that directly or indirectly impose controls on pricing.

Market acceptance of our products may depend on the availability of reimbursement by government and private third-party payors. In recent years, there have been numerous proposals to change the healthcare system in the United States. The growth of managed care organizations ("MCOs") (e.g., medical insurance companies, medical plan administrators, hospital alliances and pharmaceutical benefit managers) has placed increase pressure on drug prices and on overall healthcare expenditures. MCOs and government and other private third-party payors increasingly are attempting to contain health care costs by limiting both the coverage and the level of reimbursement of drug products. Consequently, the reimbursement status of our products is highly uncertain and we cannot assure that third-party coverage will be available or that available third-party coverage or payment will be adequate.

Other Risks

HealthCare Ventures V, L.P., HealthCare Ventures VI, L.P., and HealthCare Ventures VII, L.P. have substantial control over our business, and the interests of the HealthCare Ventures partnerships may not be consistent with the interests of our other stockholders.

HealthCare Ventures V, L.P., HealthCare Ventures VI, L.P. and HealthCare Ventures VII, L.P. currently beneficially own an aggregate of 31.5% of our outstanding common stock. James H. Cavanaugh and Harold R. Werner, members of our board of directors, are general partners of HealthCare Partners V, L.P., HealthCare Partners VI, L.P., and HealthCare Partners VII, L.P., which are the general partners of HealthCare Ventures V, L.P., HealthCare Ventures VI, L.P. and HealthCare Ventures VII, L.P., respectively. Accordingly, the HealthCare Ventures partnerships are able to exert significant influence over all matters requiring stockholder approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets, as well as over the day-to-day management of our business. The HealthCare Ventures partnerships may direct our affairs in a manner that is not consistent with the interests of our other stockholders. In addition, this concentration of ownership could have the effect of delaying, deferring or preventing a change in control, or impeding a merger or consolidation, takeover or other business combination or a sale of all or substantially all of our assets.

Future sales of our common stock, or the perception that these sales may occur, could depress our stock price.

Sales of substantial amounts of our common stock in the public market, or the perception in the public markets that these sales may occur, could cause the market price of our common stock to decline. This could also impair our ability to raise additional capital through the sale of our equity securities. Selling of a large number of shares by any of our existing shareholders or management shareholders could cause the price of our common stock to decline. Furthermore, if we file a registration statement to offer additional shares of our common stock and have to include shares held by those holders, it could impair our ability to raise needed capital by depressing the price at which we

could sell our common stock. As a result of private placements by us in 2005 and 2006, we currently have two outstanding shelf registration statements permitting investors in these private placements to publicly resell shares of our common stock.

Our certificate of incorporation and provisions of Delaware law could discourage a takeover you may consider favorable or could cause current management to become entrenched and difficult to replace.

Provisions in our certificate of incorporation and Delaware law may have the effect of delaying or preventing a merger or acquisition of us, or making a merger or acquisition less desirable to a potential acquirer, even when the stockholders may consider the acquisition or merger favorable. Under the terms of our certificate of incorporation, we are authorized to issue 25 million shares of "blank check" preferred stock, and to determine the price, privileges, and other terms of these shares. The issuance of any preferred stock with superior rights to our common stock could reduce the value of our common stock. In particular, specific rights we may grant to future holders of preferred stock could be used to restrict an ability to merge with or sell our assets to a third party, preserving control by present owners and management and preventing you from realizing a premium on your shares.

In addition, we are subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder's acquisition of our stock was approved in advance by our board of directors. These provisions could affect our stock price adversely.

The price of our common stock has been and will likely continue to be volatile.

Prior to our October 2003 initial public offering, there was no public market for our common stock. The initial public offering price of our common stock was $10.00 per share. Since our initial public offering, the price of our common stock has been as high as $10.30 and as low as $0.86 per share. Some companies that have had volatile market prices for their securities have been subject to securities class action suits filed against them. If a suit were to be filed against us, regardless of the outcome, it could result in substantial costs and a diversion of our management's attention and resources. This could have a material adverse effect on our business, results of operations and financial condition.

We could be forced to pay liquidated damages if we do not maintain the effectiveness of our S-3 registration statements.

In December 2006, we completed a private placement of 6,000,000 shares of common stock at a price of $3.00 per share, resulting in gross proceeds of $18.0 million. In April 2005, we completed a private placement of 6,846,735 shares of our common stock at a price of $3.98 per share and warrants to purchase a total of 2,396,357 shares of common stock at an exercise price of $4.78 per share, resulting in gross proceeds of $27.25 million. Pursuant to the terms of the registration rights agreements, we filed with the SEC shelf registration statements on Form S-3 covering resales of common stock. The registration rights agreement in each transaction provides that if a registration statement is not effective within a specified number of days of closing, or if we do not subsequently maintain the effectiveness of the registration statement, then in addition to any other rights the investor may have, we will be required to pay the investor liquidated damages in cash.

The SEC declared each of our Form S-3s effective within the specified number of days of closing. However, if we fail to maintain the effectiveness of the registration statements in the future, liquidated damages could be substantial.

Item 1B. ***Unresolved Staff Comments***

Not applicable.

Item 2. ***Properties***

Our principal executive offices are located in an approximately 62,000 square foot facility in Germantown, Maryland. We moved into this facility in May 2003 and completed the transfer of our laboratory function to this facility in December 2003. The lease for this facility expires in June 2013.

In August 2004, we entered into a lease for approximately 53,000 square feet of additional research and development space, in a building adjacent to the Company's existing headquarters in Germantown, Maryland. The lease for this facility expires in May 2013.

We previously had an approximately 8,432 square foot lab and office facility in Gaithersburg, Maryland, the lease for which expired in November 2005. Also, in September 2004 we rented an office of approximately 6,681 square feet for engineering space in Bridgewater, New Jersey under a short-term lease that expired in September 2006.

We believe that our facilities are suitable and adequate to meet our current needs.

Item 3. ***Legal Proceedings***

We are not a party to any material pending legal proceedings, other than ordinary routine litigation incidental to our business, except as discussed below.

In December 2003, Aventis and Aventis Pharmaceuticals Inc., now part of sanofi-aventis, brought an action against Advancis, alleging, in essence, that the Advancis corporate name is infringing the plaintiff's trademark and seeking injunctive relief. A trial was held in May 2005, and the Court's decision, dated September 26, 2006, ruled in favor of sanofi-aventis and required the parties to jointly submit a proposed Permanent Injunction and Order, which was submitted on October 27, 2006. On October 31, 2006 the proposed Order was approved, under which Advancis will surrender its trademark registrations for the "Advancis" name, and cease using the name in connection with our business, effective June 30, 2007.

No monetary damages were associated with the decision, and we do not believe there will be a significant financial impact in complying with the Court's decision.

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

No matters were submitted to a vote of our security holders during the fourth quarter of the fiscal year ended December 31, 2006.

PART II

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

Our common stock has been traded on The Nasdaq National Market under the symbol AVNC since October 17, 2003. The following table sets forth the quarterly high and low sales prices per share of our common stock as reported by Nasdaq for each quarter during the last two fiscal years, commencing on January 1, 2005:

	High	Low
December 31, 2006:		
Fourth quarter	$5.90	$3.23
Third quarter	6.70	2.79
Second quarter	3.98	2.50
First quarter	3.72	1.23
December 31, 2005:		
Fourth quarter	$1.69	$1.20
Third quarter	2.75	0.86
Second quarter	5.40	1.70
First quarter	5.42	3.03

As of February 26, 2007, there were 94 holders of record of our common stock. This figure does not represent the actual number of beneficial owners of our common stock because shares are generally held in "street name" by securities dealers and others for the benefit of individual owners who may vote the shares.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends for the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in current or future financing instruments and such other factors as our board of directors deems relevant.

Item 6. *Selected Financial Data*

The following selected financial information has been derived from the audited financial statements. The information below is not necessarily indicative of results of future operations and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-K and the financial statements and related notes thereto included in Item 8 of this Form 10-K in order to fully understand factors that may affect the comparability of the information presented below.

	For the Years Ended December 31,				
	2006	2005	2004	2003	2002
Statements of Operations Data					
Total revenue	$ 4,810,410	$ 16,847,690	$ 11,358,032	$ 3,625,000	$ —
Cost and expenses:					
Cost of product sales	899,601	562,009	169,854	—	—
Research and development	25,973,844	39,729,441	33,642,930	16,594,629	10,855,130
Selling, general and administrative	21,288,968	10,515,302	12,219,409	6,427,453	3,323,879
Total expenses	48,162,413	50,806,752	46,032,193	23,022,082	14,179,009
Loss from operations	(43,352,003)	(33,959,062)	(34,674,161)	(19,397,082)	(14,179,009)
Interest income (expense), net	385,034	954,193	669,448	88,565	102,629
Beneficial conversion feature — deemed interest	—	—	—	(1,666,667)	—
Other income or (expense)	976,815	16,292	—	—	(47,615)
Net loss	(41,990,154)	(32,988,577)	(34,004,713)	(20,975,184)	(14,123,995)
Accretion of issuance costs of mandatorily redeemable convertible preferred stock	—	—	—	(209,173)	(73,925)
Beneficial conversion feature — deemed dividend to preferred shareholders	—	—	—	(20,907,620)	—
Net loss applicable to common stockholders	$ (41,990,154)	$ (32,988,577)	$(34,004,713)	$(42,091,977)	$(14,197,920)
Basic and diluted net loss per share	$ (1.38)	$ (1.20)	$ (1.50)	$ (7.58)	$ (16.37)
Shares used in computing net loss per share, basic and diluted	30,535,965	27,421,516	22,684,410	5,554,773	867,239
Balance Sheet Data at Year-End:					
Unrestricted cash, cash equivalents and marketable securities	$ 15,379,461	$ 29,431,058	$ 30,051,937	$ 65,087,122	$ 4,059,911
Total assets	42,005,769	57,796,892	61,142,140	84,174,843	9,058,523
Long-term debt, including current portion	6,963,889	1,567,412	2,577,387	2,440,588	1,730,934
Mandatorily redeemable convertible preferred stock	—	—	—	—	28,439,295
Accumulated deficit	(153,085,462)	(111,095,308)	(78,106,731)	(44,102,018)	(23,126,834)
Total stockholders' equity (deficit)	11,872,020	33,342,011	39,738,379	70,149,920	(22,701,459)

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

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed financial statements and the related notes included elsewhere in this annual report on Form 10-K. This discussion may contain forward-looking statements, the accuracy of which involve risks and uncertainties. As a result of many factors, such as those set forth under the *"Forward-Looking Statements"* and *"Factors that May Affect our Business"* sections in Part 1, Item 1 and elsewhere in this annual report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.

Our Business

Advancis Pharmaceutical Corporation was incorporated in Delaware in December 1999 and commenced operations on January 1, 2000. We are a pharmaceutical company focused on developing and commercializing anti-infective drug products that fulfill unmet medical needs in the treatment of infectious disease. We are developing a portfolio of drugs based on our novel biological finding that bacteria exposed to antibiotics in front-loaded, sequential bursts, or pulses, are killed more efficiently than those exposed to standard antibiotic treatment regimens. We currently have 25 issued U.S. patents and two issued foreign patent covering our proprietary once-a-day pulsatile delivery technology called PULSYS. We have initially focused on developing PULSYS product candidates utilizing approved and marketed drugs that no longer have patent protection or that have patents expiring in the next several years. Our lead pulsatile product candidate, based on the antibiotic amoxicillin, completed a successful pivotal Phase III clinical trial in August 2006, and our Keflex PULSYS product candidate, based on the antibiotic cephalexin, is currently under evaluation in Phase I clinical trials. Our New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for our Amoxicillin PULSYS product for adults and adolescents with pharyngitis and/or tonsillitis is currently under FDA review. We also have a number of additional pulsatile product candidates in preclinical development. Continued development of additional PULSYS product candidates has been postponed and will require us to obtain additional financing. We acquired the U.S. rights to Keflex (cephalexin) from Eli Lilly in 2004, including the rights to sell Keflex capsules in 250 mg and 500 mg strengths. We currently sell our line of Keflex products to wholesalers, and have received FDA approval for two additional Keflex strengths — 333 mg capsules and 750 mg capsules. We decided to focus our commercialization initiatives solely on the Keflex 750 mg capsules. In support of the launch of the Keflex 750 mg capsules, and in anticipation of our first potential pulsatile product, Amoxicillin PULSYS, we have entered into an agreement with a contract sales organization for the deployment of approximately 75 contract sales representatives across the United States. We have also entered into agreements with third-party contract manufacturers for the commercial supply of our products.

General

Our future operating results will depend largely on our ability to raise additional capital and, assuming we raise sufficient additional capital, to successfully develop and commercialize our lead product, Amoxicillin PULSYS, successfully commercializing our Keflex 750 mg product, and the progress of other product candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in this annual report on Form 10-K.

Management Overview of Key Developments in 2006

The following is a summary of key events that occurred in 2006.

Amoxicillin PULSYS Product Development

- In September 2005, after extensive evaluation of the data from our unsuccessful Amoxicillin PULSYS Phase III clinical trials, we decided to conduct a new Phase III clinical trial for adults and adolescents, extending the length of treatment from seven days to 10 days, using our existing formulation of Amoxicillin PULSYS. Our Phase III trial began in November 2005 and was designed to support product approval for Amoxicillin PULSYS for the treatment of adolescents and adults with acute pharyngitis and/or tonsillitis

due to Group A streptococcal infections. Study enrollment concluded on May 31, 2006, with a total of 620 patients.

- On August 10, 2006, we announced that our Amoxicillin PULSYS Phase III clinical trial achieved its desired clinical and microbiological endpoints. The trial demonstrated statistical non-inferiority of Amoxicillin PULSYS therapy versus the penicillin comparator therapy for the trial's primary endpoints of bacterial eradication rates for two distinct patient populations. The trial also demonstrated Amoxicillin PULSYS reached 85 percent bacterial eradication for the "per protocol" group of patients, in accordance with FDA guidance for product approval as first-line pharyngitis therapy. Based on the successful Phase III trial data, we submitted a NDA for Amoxicillin PULSYS on December 14, 2006.

- On February 12, 2007, we received a "refusal to file" letter from the FDA for our Amoxicillin PULSYS NDA, requesting additional information on our planned commercial manufacturing processes. In its letter, the FDA indicated that our application was not sufficiently complete in that it did not include a proposed commercial batch record or a detailed commercial process description with process parameters and in-process controls. We conducted a meeting with the FDA regarding our Amoxicillin PULSYS NDA on February 26, 2007. In that meeting, we reached agreement with the FDA on the additional information that is required for our NDA filing to be accepted, which was resubmitted on March 23, 2007. The FDA did not raise any clinical or other issues in its communication.

Marketed Products — Keflex Capsules (Cephalexin USP)

- In 2006, net sales of our branded capsule Keflex products were approximately $4.8 million.

- On December 20, 2005, we filed a supplemental NDA for two new strengths of our Keflex product with the FDA. In April 2006, an FDA pre-approval inspection was initiated at our third-party contract manufacturing facility operated by Ceph International, a subsidiary of Patheon, Inc., in Puerto Rico.

- On May 12, 2006, the FDA approved our supplemental NDA for two new strengths of our Keflex antibiotic. We received approval to market 333 mg and 750 mg Keflex capsules. We made the decision to commercialize only the 750 mg strength product.

- In June 2006, we announced that we entered into an agreement with Innovex, the commercialization division of Quintiles Transnational Corp., to provide us contract sales and marketing services in support of the new Keflex 750 mg strength. Terms of the agreement include the training, hiring, and deployment of 75 contract sales representatives targeting high Keflex-prescribing physicians across the United States.

- On July 25, 2006, we announced that Keflex 750 mg capsules had been manufactured, packaged, and were shipping to pharmacies nationwide. Our contract sales representatives began directly promoting Keflex 750 mg capsules to targeted physicians as well as providing patient starter samples in late July 2006. We believe that Keflex 750 mg is currently stocked in a more than 25,000 U.S. pharmacies.

- We continued development work on a PULSYS version of Keflex, completing four additional Phase I studies during 2006, evaluating the pharmacokinetic profiles of various combinations of pulsatile cephalexin formulations.

$12 Million Credit Facility

- On June 30, 2006, we closed a $12 million secured credit facility with Merrill Lynch Capital, consisting of an $8 million term loan and a $4 million revolving loan facility. The term loan was drawn in its entirety at closing, and matures in three years. The revolving loan facility matures 45 months from the closing date, and credit available under this facility will be determined based on a percentage of our accounts receivable. We used the proceeds from the credit facility for general working capital and plan to repay borrowings with cash flow from operations.

Private Placement of Common Stock

- In December 2006, we completed a private placement of 6,000,000 shares of our common stock at a price of $3.00 per share, resulting in net proceeds to us, after the deduction of fees and commissions, of $16.7 million.

Advancis Corporate Name Change

- In October 2006, we jointly submitted a proposed Permanent Injunction and Order with sanofi-aventis, pursuant to a U.S. Court Opinion and Order issued September 26, 2006, ruling that the Advancis corporate name is infringing the sanofi-aventis trademark. Following this joint submission, we have been actively involved in the process of selecting a new corporate name. We have made significant progress to date and expect to effect an orderly transition to our new corporate identity in the first half of 2007.

Focus for 2007

Our primary focus for 2007 will be on the submission of our NDA and the regulatory approval process for our Amoxicillin PULSYS product candidate for adults and adolescents, along with the continued commercialization of our Keflex 750 mg capsules. We resubmitted our NDA supporting Amoxicillin PULSYS marketing approval on March 23, 2007 and could potentially have the application accepted for filing by the FDA in May 2007. Should our NDA be accepted by the FDA, we anticipate initiating our commercial manufacturing processes and commencing our commercialization initiatives over the year, in preparation for a potential launch of the product by as soon as early 2008. We intend to continue promoting the new Keflex 750 mg capsules through our approximately 75 contract sales representatives and seven Advancis district sales managers to targeted U.S. physicians throughout the remainder of 2007. In order to minimize our financing requirements in 2007, we have initiated cost reductions including personnel reductions, postponement of PULSYS clinical development programs other than Amoxicillin PULSYS for adults, and elimination of other discretionary spending.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, fair valuation of stock related to stock-based compensation and income taxes. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We recognize revenue for the sale of pharmaceutical products and for payments received, if any, under collaboration agreements for licensing, milestones, and reimbursement of development costs as follows:

Product Sales. Revenue from product sales, net of estimated provisions, is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the selling price is fixed or determinable, and collectibility is reasonably probable. Our customers consist primarily of large pharmaceutical wholesalers who sell directly into the retail channel. Provisions for sales discounts, and estimates for chargebacks, rebates, and product returns are established as a reduction of product sales revenue at the time revenues are recognized, based on historical experience adjusted to reflect known changes in the factors that impact these reserves. Factors include current contract prices and terms, estimated wholesaler inventory levels, remaining shelf life of product, and historical information for similar products in the same distribution channel. These revenue reductions are generally

reflected either as a direct reduction to accounts receivable through an allowance, or as an addition to accrued expenses if the payment is due to a party other than the wholesaler.

Chargebacks and rebates. We record chargebacks and rebates based on the difference between the prices at which we sell our products to wholesalers and the sales price ultimately paid under fixed price contracts by third party payers, including governmental agencies. We record an estimate at the time of sale to the wholesaler of the amount to be charged back to us or rebated to the end user. We have recorded reserves for chargebacks and rebates based upon various factors, including current contract prices, historical trends, and our future expectations. The amount of actual chargebacks and rebates claimed could be either higher or lower than the amounts we accrued. Changes in our estimates would be recorded in the income statement in the period of the change.

Product returns. In the pharmaceutical industry, customers are normally granted the right to return product for a refund if the product has not been used prior to its expiration date, which for our Keflex product is typically three years from the date of manufacture (two years, in the case of oral suspension products). Our return policy typically allows product returns for products within an eighteen-month window from six months prior to the expiration date and up to twelve months after the expiration date. We estimate the level of sales which will ultimately be returned pursuant to our return policy, and record a related reserve at the time of sale. These amounts are deducted from our gross sales to determine our net revenues. Our estimates take into consideration historical returns of our products and our future expectations. We periodically review the reserves established for returns and adjust them based on actual experience. The amount of actual product returns could be either higher or lower than the amounts we accrued. Changes in our estimates would be recorded in the income statement in the period of the change. If we over or under estimate the quantity of product which will ultimately be returned, there may be a material impact to our financial statements.

Contract Revenue. We use the milestone payment method of revenue recognition when all milestones in respect of payments to be received under contractual arrangements are determined to be substantive, at-risk and the culmination of an earnings process. Substantive milestones are payments that are conditioned upon events requiring substantive effort, when the amounts of the milestones are reasonable relative to the time, effort and risk involved in achieving them and when the milestones are reasonable relative to each other and the amount of any up-front payment. If these criteria are not met, the timing of the recognition of revenue from the milestone payment may vary. Up-front payments are recorded as deferred revenue. We estimate the length of the remaining development period and amortize an up-front payment over that development period.

Reimbursement of Development Costs. We record revenue for reimbursement of development costs as the actual costs to perform the work are incurred. We are required to use judgment in recognizing reimbursement revenue in cases where the agreement provides for funding to us that is not dependent on actual costs we incur within a specific fiscal period. Our policy is to limit revenue recognized to the minimum amounts expected under a specific collaboration agreement and to exclude amounts contingent on future events, such as successful commercialization and future profit-sharing, and amounts that are contingently refundable. Revenue recognized is limited to cumulative amounts under each contract such that, at any time, if a termination of the agreement were to occur, revenue previously recognized would not need to be reversed. Cash received in excess of revenue recognized is recorded as deferred revenue, with the deferred revenue recognized as revenue at the time future events occur that remove the contingencies.

Inventories

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out method. Inventory consists of Keflex finished capsules and finished oral suspension powder. We purchase our Keflex products from third-party manufacturers only at the completion of the manufacturing process, and accordingly have no raw material or work-in-process inventories. At least on a quarterly basis, we review our inventory levels and write down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value or is in excess of expected requirements. Inventory levels are evaluated by management relative to product demand, remaining shelf life, future marketing plans and other factors, and reserves for obsolete and slow-moving inventories are recorded for amounts which may not be realizable.

Intangible Assets

Acquired Intangible Assets. We acquired the U.S. rights to the Keflex brand of cephalexin in 2004. We may acquire additional pharmaceutical products in the future that include license agreements, product rights and other identifiable intangible assets. When intangible assets are acquired, we review and identify the individual intangible assets acquired and record them based on relative fair values. Each identifiable intangible asset is then reviewed to determine if it has a definite life or indefinite life, and definite-lived intangible assets are amortized over their estimated useful lives.

Impairment. We assess the impairment of identifiable intangible assets on an annual basis or when events or changes in circumstances indicate that the carrying value may not be recoverable. Some factors we consider important which could trigger an impairment review include significant underperformance compared to historical or projected future operating results, significant changes in our use of the acquired assets or the strategy for our overall business, or significant negative industry or economic trends. If we determine that the carrying value of intangible assets may not be recoverable based upon the existence of one or more of these factors, we first perform an assessment of the asset's recoverability based on expected undiscounted future net cash flow, and if the amount is less than the asset's value, we measure any impairment based on a projected discounted cash flow method using a discount rate determined by our management to be commensurate with the risk inherent in our current business model.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses for services performed and liabilities incurred. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated accrued expenses for services include professional service fees, such as lawyers and accountants, contract service fees, such as amounts paid to clinical monitors, data management organizations and investigators in conjunction with clinical trials, fees paid to our contract sales organization, and fees paid to contract manufacturers in conjunction with the production of clinical materials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often judgmental. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles. We also make estimates for other liabilities incurred, including health insurance costs for our employees. We are self-insured for claims made under our health insurance program and record an estimate at the end of a period for claims not yet reported. Our risk exposure is limited, as claims over a maximum amount are covered by an aggregate stop loss insurance policy.

Stock-Based Compensation

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123R, *"Share-Based Payment"* (SFAS 123R). We adopted SFAS 123R using the modified prospective transition method, which requires the recognition of compensation expense under the Statement on a prospective basis only. Accordingly, prior period financial statements have not been restated. Under this transition method, stock-based compensation cost for the twelve months ended December 31, 2006 includes (a) compensation cost for all share-based awards granted prior to, but not yet vested as of, January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all share-based awards granted subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the fair value provisions of SFAS 123R.

SFAS 123R also requires us to estimate forfeitures in calculating the expense related to share-based compensation rather than recognizing forfeitures as a reduction in expense as they occur. To the extent actual

forfeitures differ from our estimates, such amounts will be recorded as a cumulative adjustment in the period that the estimates are revised. We plan to refine our estimated forfeiture rate as we obtain more historical data.

We determine the value of stock option grants using the Black-Scholes option-pricing model. Our determination of fair value of share-based payment awards on the date of grant is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards and projected employee stock option exercise behaviors. This model requires that we estimate our future expected stock price volatility as well as the period of time that we expect the share-based awards to be outstanding.

- We have elected to determine the expected term of share-based awards granted subsequent to January 1, 2006 using the transition approach provided by Staff Accounting Bulletin No. 107, under which an expected term of 6.25 years may be used for four-year grants with ten-year contractual terms. We plan to refine our estimate of expected term in the future as we obtain more historical data. A shorter expected term would result in lower compensation expense.
- To estimate expected future volatility, we considered several factors and data sets, including available information from our limited trading history, as well as the reported volatility rates of other comparable public companies. We have no implied volatility data since we have no publicly traded options or other financial instruments from which implied volatility can be derived. For the expected future volatility factor computed for input to the Black-Scholes model, we primarily used a combination of our historical volatility together with the average of volatility rates of comparable public companies. Using a higher volatility input to the Black-Scholes model would result in a higher compensation expense.
- The risk-free rate is based on U.S. Treasury yields in effect at the time of grant corresponding with the expected term of the options. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by the employees who receive equity awards.

Income Taxes

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have not recorded any tax provision or benefit for the years ended December 31, 2006, 2005 and 2004. We have provided a valuation allowance for the full amount of our net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry forwards cannot presently be sufficiently assured. At December 31, 2006 and 2005, we had federal and state net operating loss carryforwards of approximately $120.6 million and $78.3 million, respectively, available to reduce future taxable income, which will begin to expire in 2020. Under the provisions of Section 382 of the Internal Revenue Code, certain substantial changes in our ownership may result in a limitation on the amount of net operating loss and research and experimentation tax credit carry forwards which can be used in future years. During 2001 and 2005, we may have experienced such ownership changes. Ownership changes in 2001 and 2005 may have created annual limitations of approximately $0.9 million and $3.8 million, respectively. There were no ownership changes under Section 382 in other years.

Recent Accounting Pronouncements

Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123R, *"Share-Based Payment,"* (SFAS 123R), a revision of SFAS 123, *"Accounting for Stock-based Compensation."* SFAS 123R requires public companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use APB Opinion 25's intrinsic value method of accounting for share-based payments. We selected the modified prospective method of adoption. Under this method, compensation expense

recognized by us for the twelve month period ended December 31, 2006 included: (a) compensation expense for all share-based payments granted prior to, but not vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation expense for all share-based payments granted on or after January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. Results for prior periods were not restated. See Notes 15 and 16 to the financial statements for more details on stock-based compensation.

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48 ("FIN 48"), *"Accounting for Uncertainty in Income Taxes,"* an interpretation of FASB Statement No. 109 ("SFAS 109"). The interpretation clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS 109, *"Accounting for Income Taxes."* It prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken on a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the impact, if any, of FIN 48 on our financial statements.

In September 2006, the FASB issued SFAS No. 157, *"Fair Value Measurements"* (SFAS 157), which provides guidance for how companies should measure fair value when required to use a fair value measurement for recognition or disclosure purposes under generally accepted accounting principle (GAAP). SFAS 157 is effective for fiscal years beginning after November 15, 2007. We are currently assessing the impact, if any, the adoption of SFAS 157 will have on our financial statements.

In December 2006, FASB Staff Position No. EITF 00-19-2, *"Accounting for Registration Payment Arrangements,"* was issued. The FSP specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with SFAS No. 5, *"Accounting for Contingencies."* We believe that our current accounting is consistent with the FSP. Accordingly, adoption of the FSP had no effect on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *"The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115"*, under which entities will now be permitted to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis. This Statement is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Early adoption is permitted as of the beginning of a fiscal year that begins on or before November 15, 2007, provided the entity also elects to apply the provisions of SFAS 157. We are currently assessing the impact, if any, the adoption of SFAS 159 will have on our financial statements.

Research and Development Expenses

We expect our research and development expenses to be significant as we continue to develop our product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers in conjunction with independently monitoring our clinical trials and acquiring and evaluating data in conjunction with our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, depreciation of capital resources used to develop our products, and costs of facilities. We expense research and development costs as incurred. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates and proprietary technologies.

Summary of Product Development Initiatives. The following table summarizes our product development initiatives for the fiscal years ended December 31, 2006, 2005 and 2004. Included in this table is the research and development expense recognized in connection with each product candidate currently in clinical development and all preclinical product candidates as a group.

See *"Our Product Pipeline"* above for our current priority product candidates.

	Year Ended December 31,			Total Expense Incurred from Inception (January 1, 2000) to December 31, 2006	Clinical Development Phase
	2006	2005	2004		
Direct Project Costs(1)					
Amoxicillin PULSYS(2)	$12,354,000	$24,294,000	$15,961,000	$ 60,484,000	NDA submitted
Keflex Product Development(3)	5,424,000	5,360,000	222,000	11,006,000	Phase I (on hold)
Generic Clarithromycin(4)	—	79,000	5,480,000	15,579,000	Suspended
Other Product Candidates	863,000	1,289,000	4,108,000	16,108,000	Preclinical
Total Direct Project Costs	18,641,000	31,022,000	25,771,000	103,177,000	
Indirect Project Costs(1)					
Facility	3,136,000	3,603,000	2,954,000	12,101,000	
Depreciation	2,441,000	2,610,000	1,928,000	8,319,000	
Other Indirect Overhead	1,756,000	2,494,000	2,990,000	9,627,000	
Total Indirect Expense	7,333,000	8,707,000	7,872,000	30,047,000	
Total Research & Development Expense	$25,974,000	$39,729,000	$33,643,000	$133,224,000	

(1) Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record direct costs, including personnel costs and related benefits and stock-based compensation, on a project-by-project basis. We record indirect costs that support a number of our research and development activities in the aggregate.

(2) On August 10, 2006, we announced that our Amoxicillin PULSYS Phase III clinical trial achieved its desired clinical and microbiological endpoints. The trial demonstrated statistical non-inferiority of Amoxicillin PULSYS therapy versus the penicillin comparator therapy for the trial's primary endpoints of bacterial eradication rates for two different patient populations. We resubmitted our New Drug Application for Amoxicillin PULSYS to the FDA on March 23, 2007. See *"Amoxicillin PULSYS"* above. We previously had an agreement under which Par Pharmaceutical was to be responsible for funding the anticipated future development costs of this product. See *"Termination of Our Collaboration with Par Pharmaceutical for Amoxicillin PULSYS"* above.

(3) Direct Project Costs for Keflex product development include development costs for the non-pulsatile Keflex 750 mg and Keflex 333 mg line extension products, which commercially launched in July 2006, as well as research and development costs for a once-a-day Keflex PULSYS product, currently in Phase I clinical trials. Additional development of Keflex PULSYS is on hold, until we have sufficient financial resources.

(4) We have discontinued development efforts for this product. See *"Our Collaboration with Par Pharmaceutical for Generic Clarithromycin"* above.

Net Losses

We have a limited history of operations. We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including progress of our research and development efforts, approval and commercial launch of new products, and the timing and outcome of regulatory approvals. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of December 31, 2006, we had an accumulated deficit of approximately $153.1 million. We anticipate incurring additional annual losses, perhaps at higher levels, for the foreseeable future.

Results of Operations

Fiscal Year Ended December 31, 2006 Compared to Fiscal Year Ended December 31, 2005

Revenues. We recorded revenues of $4.8 million during the fiscal year ended December 31, 2006 compared to $16.8 million during the fiscal year ended December 31, 2005, as follows:

	2006	2005
Keflex product sales — net	$4,810,000	$ 4,809,000
Amortization of upfront license fee — Par amoxicillin	—	4,028,000
Reimbursement of development costs — Par amoxicillin	—	8,011,000
Total	$4,810,000	$16,848,000

Prior to the third quarter of 2006, net product sales consist primarily of shipments of the Keflex 250 and 500 milligram strengths to wholesalers. In July 2006, we launched a 750 milligram strength capsule, supported by a targeted and dedicated national contract sales force of 75 sales representatives and eight Advancis district sales managers. During the year, we recognized $2.7 million of revenue related to sales of the 750 mg product, which includes initial stocking to wholesalers and pharmacies. Net revenues for other Keflex products was $2.1 million, consisting entirely of net product sales of Keflex 250 and 500 capsules, as compared to $4.8 million in 2005. The decrease in Keflex sales compared to prior periods was mainly due to a net reduction in orders received from our wholesaler customers for our Keflex 250 and 500 products. In addition, there is increasing substitution of generic cephalexin for prescriptions of existing 250 mg and 500 mg Keflex brand capsules. Net product sales of our oral suspension Keflex product were insignificant for the periods presented.

Revenues recognized in 2005 for amortization of upfront licensing fees represent the amortization of a $5.0 million upfront payment received from Par Pharmaceutical in May 2004 in connection with our collaboration for Amoxicillin PULSYS, which was being amortized into revenue on a straight-line basis over the estimated development period. On August 3, 2005, Par terminated the Amoxicillin PULSYS collaboration, at which time we recognized the remaining deferred revenue balance of $3.2 million.

Reimbursement of development costs by Par was recognized based on the related costs incurred. As a result of the contract termination by Par on August 3, 2005, we accelerated the revenue recognition of $2.4 million in the third quarter, which was the remaining deferred revenue balance in excess of the amount retained for future contingent liability to Par.

Cost of Product Sales. Cost of product sales represents the purchase cost of the Keflex products sold during the year as well as royalties, if applicable. Cost of product sales increased from $0.6 million in 2005 to $0.9 million in 2006, as a result of purchase and royalty costs associated with the 750 milligram product launched in 2006.

Research and Development Expenses. Research and development expenses decreased $13.7 million, or 35%, to $26.0 million for the fiscal year ended December 31, 2006 from $39.7 million for the fiscal year ended December 31, 2005. Research and development expenses consist of direct costs which include salaries and related costs of research and development personnel, and the costs of consultants, materials and supplies associated with research and development projects, as well as clinical studies. Indirect research and development costs include facilities, depreciation, and other indirect overhead costs.

The following table discloses the components of research and development expenses reflecting our project expenses.

Research and Development Expenses	Year Ended December 31, 2006	2005
Direct project costs:		
Personnel, benefits and related costs	$ 6,252,000	$10,716,000
Stock-based compensation	1,435,000	160,000
Consultants, supplies, materials and other direct costs	4,916,000	7,912,000
Clinical studies	6,038,000	12,234,000
Total direct costs	18,641,000	31,022,000
Indirect project costs	7,333,000	8,707,000
Total	$25,974,000	$39,729,000

Personnel, benefits and related costs decreased $4.5 million in 2006 primarily due to severance charges of $2.8 million incurred in 2005, versus zero in 2006, and a benefit of $1.5 million due to lower staffing levels throughout 2006 attributable to reductions in staff implemented in 2005. Stock-based compensation costs increased $1.3 million, of which $0.9 million is related to employees and results primarily from the impact of adoption of SFAS 123R in 2006, and the remaining increase of $0.4 million relates to expense for non-employees, which increased from the impact of a higher stock price in 2006 versus 2005 as well as grants for the first time to contracted sales representatives.

Consultants, supplies, materials and other direct costs decreased $3.0 million, a result of decreased spending of $1.7 million on Amoxicillin PULSYS materials, a reduction in pediatric amoxicillin costs of $0.9 million as we refocused on passing the adult trial, and reductions in other projects of $0.4 million. Clinical trials expense decreased $6.2 million overall, as we conducted a single phase III amoxicillin trial in 2006, versus two trials in 2005.

Indirect project costs decreased by $1.4 million, primarily due to decreases in facility-related costs of $0.5 million from vacating the Gaithersburg facility in 2005, consulting costs of $0.6 million, and equipment depreciation of $0.2 million as some equipment became fully depreciated while new acquisitions were minimal.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $10.8 million, or 102%, to $21.3 million for the year ended December 31, 2006 from $10.5 million for the year ended December 31, 2005.

	Year Ended December 31, 2006	2005
Salaries, benefits and related costs	$ 2,351,000	$ 3,387,000
Stock-based compensation	1,970,000	376,000
Legal and consulting expenses	2,142,000	1,342,000
Other expenses	6,175,000	5,410,000
Marketing costs	3,786,000	—
Contract sales expenses	4,865,000	—
Total	$21,289,000	$10,515,000

Selling, general and administrative expenses consist of salaries and related costs for executive and other administrative personnel, selling and product distribution costs, professional fees and facility costs. Major increases in 2006 include costs of promoting sales of our Keflex 750 mg line extension, including the addition of eight district sales managers, engaging a third party sales organization, and other marketing activities in support of the product line extension.

Salaries, benefits and related costs decreased $1.0 million versus 2005, due to severance costs for a workforce reduction in 2005 of $1.1 million and lower compensation costs in 2006 related to the reduced number of employees

of $0.3 million, partly offset by the additional costs of the sales management team of $0.5 million in 2006 as compared to 2005.

Stock-based compensation increased $1.6 million primarily from the effect of SFAS 123R, which was effective on January 1, 2006. Also, prior year expense was relatively low due to the reversal of prior period expense of approximately $0.5 million for the forfeiture of stock options resulting from the workforce reduction in 2005.

Legal and consulting costs increased $0.8 million as we engaged outside organizations to conduct extensive market research in support of its Keflex line extension and potential future products.

Other expenses increased $0.8 million as we incurred regulatory license and filing fees of $0.5 million in connection with our Keflex product line and Amoxicillin PULSYS NDA, and increased patent costs of $0.4 million.

Marketing costs of $3.8 million in 2006 reflect activities in support of the initial launch and continuing marketing of our Keflex line extension. Contract sales expenses consist of the direct costs of 75 sales representatives we have engaged through a third-party contract sales organization, to promote our Keflex 750 mg product to physicians.

Net Interest Income (Expense). Net interest income was $0.4 million for the year ended December 31, 2006 compared to net interest income of $1.0 million for the year ended December 31, 2005. While the yield on investments improved in 2006 due to modestly higher interest rates, interest income overall declined $0.2 million due to reduced cash balances available for investing during the year. Interest expense increased from 2005 as we incurred interest costs related to our Merrill Lynch term debt facility, which originated at the end of the second quarter 2006.

	Year Ended December 31,	
	2006	2005
Interest income	$ 896,000	$1,075,000
Interest expense	(511,000)	(121,000)
Total, net	$ 385,000	$ 954,000

Other Income. Other income in 2006 primarily consists of the recognition in income of a non-refundable advance payment of $1.0 million received in 2005 for the potential sale of the Keflex brand rights, as the sale was not completed.

Fiscal Year Ended December 31, 2005 Compared to Fiscal Year Ended December 31, 2004

Revenues. We recorded revenues of $16.8 million during the fiscal year ended December 31, 2005 compared to $11.4 million during the fiscal year ended December 31, 2004, as follows:

	Year Ended December 31,	
	2005	2004
Keflex product sales, net	$ 4,809,000	$ 2,397,000
Contract revenue — amortization of upfront licensing fees:		
GSK	—	1,146,000
GSK — acceleration upon termination	—	3,229,000
Par — amoxicillin	797,000	972,000
Par — amoxicillin — acceleration upon termination	3,231,000	—
Reimbursement of development costs:		
Par — amoxicillin	5,636,000	3,614,000
Par — amoxicillin — acceleration upon termination	2,375,000	—
Total	$16,848,000	$11,358,000

Product sales of Keflex commenced in July 2004, subsequent to the purchase of the brand rights in the U.S. market from Eli Lilly; therefore, results for 2004 reflect six months of sales compared to 12 months in 2005.

Revenues recognized in 2005 for amortization of upfront licensing fees include the amortization of a $5.0 million upfront payment received from Par Pharmaceutical in 2004, of which the remainder of $3.2 million was recognized in 2005 due to the termination of the collaboration agreement. Revenue for amortization of upfront licensing fees from GlaxoSmithKline in 2004 represented amortization of the $5.0 million upfront payment received from GSK in May, 2004, with no comparable amount in 2005 due to the termination of the GSK collaboration in December 2004.

Reimbursement of development costs under the Par amoxicillin PULSYS collaboration agreement was recognized as revenue based on the related costs incurred. As a result of the termination of the collaboration on August 3, 2005, we accelerated the revenue recognition of $2.4 million, which represented the remaining deferred revenue balance in excess of the amount retained for future contingent liability to Par.

Cost of Product Sales. Cost of product sales represents the purchase cost of the Keflex products sold, together with royalties due on the sale of certain Keflex products. Cost of product sales was $0.6 million in 2005 and $0.2 million in 2004.

Research and Development Expenses. Research and development expenses increased $6.1 million, or 18%, to $39.7 million for the fiscal year ended December 31, 2005 from $33.6 million for the fiscal year ended December 31, 2004. Research and development expenses consist of direct costs which include salaries and related costs of research and development personnel, and the costs of consultants, materials and supplies associated with research and development projects, as well as clinical studies. Indirect research and development costs include facilities, depreciation, and other indirect overhead costs.

The following table discloses the components of research and development expenses reflecting all of our project expenses.

Research and Development Expenses	Year Ended December 31, 2005	2004
Direct project costs:		
Personnel, benefits and related costs	$10,716,000	$ 9,522,000
Stock-based compensation	160,000	1,173,000
Consultants, supplies, materials and other direct costs	7,912,000	8,595,000
Clinical studies	12,234,000	6,481,000
Total direct costs	31,022,000	25,771,000
Indirect project costs	8,707,000	7,872,000
Total	$39,729,000	$33,643,000

Personnel, benefits and related costs increased $1.2 million in 2005 primarily due to severance charges of $2.9 million versus $0.4 million in 2004, partly offset by a benefit of $1.3 million due to lower staffing levels throughout 2005 attributable to reductions in staff in November 2004 and July 2005. Stock-based compensation costs declined $1.0 million, of which $0.9 million results from use of the FIN 28 accelerated method of amortization, and the remaining decrease is due to cancellation of options for which expense had previously been recognized.

Contract R&D, consultants, materials and other costs decreased $0.7 million, due to a reduction in costs of $1.9 million on the generic clarithromycin project that was discontinued in 2004, and reductions in other projects of $1.9 million. Partly offsetting the decreases were increased costs of $1.8 million for Keflex product development, $1.0 million for pediatric and adult amoxicillin trials, and other projects of $0.3 million. Clinical trials expense increased $5.8 million overall, due to $7.6 million increased expense in 2005 for Phase III clinical trials of adult and pediatric amoxicillin, partly offset by lower expenses for generic clarithromycin of $1.3 million and other projects of $0.5 million.

Indirect project costs also increased by $0.8 million, primarily due to an increase in facility-related costs of $0.8 million and equipment depreciation of $0.7 million, resulting from the acquisition of product manufacturing equipment used to produce amoxicillin for clinical trials, offset by changes in all other indirect expenses of $0.7 million.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $1.7 million, or 14%, to $10.5 million for the year ended December 31, 2005 from $12.2 million for the year ended December 31, 2004.

	Year Ended December 31,	
	2005	2004
Salaries, benefits and related costs	$ 3,387,000	$ 2,667,000
Stock-based compensation	376,000	2,480,000
Legal and consulting expenses	1,342,000	2,694,000
Other expenses	5,410,000	4,378,000
Total	$10,515,000	$12,219,000

Salaries, benefits and related costs in 2005 increased $0.7 million, which was primarily attributable to severance costs of $1.1 million. Stock-based compensation costs decreased a total of $2.1 million, due to a decrease of $1.1 million attributable to the use of an accelerated method of amortization to recognize employee-based option expense recognized under APB 25, a decrease of $0.5 million due to reversal of prior period expense for the forfeiture of options that resulted from the termination of employees in 2005, and a decrease of $0.5 million due to a one-time charge in 2004 for stock-based compensation related to retirement of a director.

Legal and consulting costs decreased $1.4 million due primarily to a higher level of legal activity in 2004 in support of collaboration agreement negotiations. Other expenses increased $1.0 million, which included amortization of the Keflex intangible assets of $0.6 million, and increased facilities costs of $0.4 million.

Net Interest Income (Expense). Net interest income was $1.0 million for the year ended December 31, 2005 compared to net interest income of $0.7 million for the year ended December 31, 2004. The increase is primarily attributable to higher short term interest rates in 2005 versus 2004.

	Year Ended December 31,	
	2005	2004
Interest income	$1,075,000	$ 794,000
Interest expense	(121,000)	(125,000)
Total, net	$ 954,000	$ 669,000

Liquidity and Capital Resources

We have funded our operations principally with the proceeds of $54.5 million from a series of five preferred stock offerings and one issue of convertible notes over the period 2000 through 2003, the net proceeds of $54.3 million from our initial public offering in October 2003, and private placements of common stock for net proceeds of $25.8 million and $16.7 million in April 2005 and December 2006, respectively. In addition, we have received funding of $8.0 million and $28.25 million from GlaxoSmithKline and Par Pharmaceutical, respectively, as a result of collaboration agreements for the development of new products. Since July 2004, we have also received cash of approximately $13 million from sales of our Keflex products. We received a $1.0 million advance payment in 2005 from a potential buyer of our Keflex brand, which we recognized in income in 2006 as the sale was not completed. In the second quarter of 2006, we received proceeds of $6.9 million from a term loan, net of costs and the payoff of existing debt.

We are evaluating various strategic alternatives to further enhance shareholder value, and in March 2007 we retained an investment banking firm to assist us in this regard. Strategic alternatives we may pursue could include, but are not limited to, continued execution of our operating plan, licensing or development arrangements, the sale of some or all of our company's assets, partnering or other collaboration agreements, or a merger or other strategic transaction. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

Cash and Marketable Securities

At December 31, 2006, unrestricted cash, cash equivalents and marketable securities were $15.4 million compared to $29.4 million at December 31, 2005.

	As of December 31,	
	2006	2005
Cash and cash equivalents	$14,857,000	$18,117,000
Marketable securities	522,000	11,314,000
Total	$15,379,000	$29,431,000

Our cash and cash equivalents are highly-liquid investments with a maturity of 90 days or less at date of purchase and consist of time deposits, investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. Our marketable securities are also highly-liquid investments and are classified as available-for-sale, as they can be utilized for current operations. Our investment policy requires the selection of high-quality issuers, with bond ratings of AAA to A1+/P1. Our objective is to limit the investment portfolio to a maximum average duration of approximately one year, with no individual security exceeding a two-year duration. At December 31, 2006, no security was held with a maturity greater than 6 months from that date.

Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances.

Cash Flow

The following table summarizes our sources and uses of cash and cash equivalents for fiscal years ending December 31, 2006, 2005, and 2004.

	Year Ended December 31,		
	2006	2005	2004
Net cash used in operating activities	$(36,331,000)	$(24,890,000)	$(15,487,000)
Net cash provided by (used in) investing activities	10,793,000	7,676,000	(11,721,000)
Net cash provided by financing activities	22,278,000	24,935,000	153,000
Net increase (decrease) in cash and cash equivalents	$ (3,260,000)	$ 7,721,000	$(27,055,000)

Operating Activities

Net cash used in operating activities for the three years ended December 31, 2006 is presented in the following table, which displays cash received and cash disbursed by major element.

Operating Activities	Year Ended December 31, 2006	2005	2004
Cash receipts:			
Cash received from product sales	$ 6,120,000	$ 5,159,000	$ 2,230,000
Cash received from collaboration partners	—	14,250,000	17,000,000
Interest income received and other	1,568,000	1,622,000	2,185,000
Total cash receipts	7,688,000	21,031,000	21,415,000
Cash disbursements:			
Cash paid for employee compensation and benefits	9,969,000	11,432,000	10,401,000
Cash paid to vendors, suppliers, and other	34,050,000	34,489,000	26,501,000
Total cash disbursements	44,019,000	45,921,000	36,902,000
Net cash used in operating activities	$(36,331,000)	$(24,890,000)	$(15,487,000)

Cash received from product sales in 2006 of $6.1 million exceeded product sales cash receipts in 2005 of $5.2 million, reflecting the positive impact of our introduction of the Keflex 750 mg product. 2004 product sales cash received reflects only a half-year of results, as the Keflex product was acquired from Eli Lilly mid-year. Cash received from collaboration partners relates to our previous collaboration agreements with Par Pharmaceutical for amoxicillin PULSYS and with GlaxoSmithKline for amoxicillin/clavulanate development. We received $14.25 million and $14.0 million in 2005 and 2004, respectively, from Par and $3.0 million in 2004 from GSK. Cash paid for employee compensation and benefits declined in 2006 from 2005, due to the favorable impact of a workforce reduction implemented in 2005. While cash paid to outside vendors in 2006 declined slightly from the previous year, there was a shift from funding of clinical trials expense towards commercialization as we introduced our new Keflex product.

Investing Activities

Net cash provided by/used in investing activities for the three years ended December 31, 2006 is presented in the following table, which displays cash received and cash disbursed by major element.

Investing Activities	Year Ended December 31, 2006	2005	2004
Cash receipts:			
Sale of marketable securities, net of purchases	$10,590,000	$8,176,000	$ 6,582,000
Advance payment received for potential sale of Keflex	—	1,000,000	—
Sale of fixed assets, restricted cash and other	754,000	423,000	—
Total cash receipts	11,344,000	9,599,000	6,582,000
Cash disbursements:			
Purchase of Keflex brand rights	—	—	11,206,000
Property and equipment purchases and deposits	551,000	1,923,000	6,960,000
Change in restricted cash and other	—	—	137,000
Total cash disbursements	551,000	1,923,000	18,303,000
Net cash provided by (used in) investing activities	$10,793,000	$7,676,000	$(11,721,000)

The most significant investing activities in 2006 included net purchases and sales of marketable securities of $10.6 million, the release of restricted cash of $0.7 million, and purchases and deposits on property and equipment of $0.6 million.

The most significant investing activities in 2005 included net purchases and sales of marketable securities of $8.2 million, receipt of a $1.0 million advance payment pursuant to the potential sale of Keflex assets (which we retained, as the agreement-in-principle expired without the sale of the business), and purchases of and deposits on property and equipment of $1.9 million.

Net cash used in investing activities during the year ended December 31, 2004 was $11.7 million. The most significant investing activities included the acquisition of Keflex intangibles for $11.2 million, and purchases of and deposits on property and equipment of $7.0 million. Net purchases and sales of marketable securities provided $6.6 million during the period.

Financing Activities

Net cash provided by financing activities for the three years ended December 31, 2006 is presented in the following table, which displays cash received and cash disbursed by major element.

	Year Ended December 31,		
Financing Activities	**2006**	**2005**	**2004**
Cash receipts:			
Cash received from private placement	$16,736,000	$25,844,000	$ —
Cash received from lines of credit and debt	7,793,000	—	1,390,000
Cash received from preferred stock and notes	—	—	—
Cash received from exercise of stock options	353,000	101,000	16,000
Total cash receipts	24,882,000	25,945,000	1,406,000
Cash disbursements:			
Cash paid for debt payments	2,604,000	1,010,000	1,253,000
Total cash disbursements	2,604,000	1,010,000	1,253,000
Net cash provided by financing activities	$22,278,000	$24,935,000	$ 153,000

The major financing activities in 2006 were a private placement of common stock, which provided $16.7 million net of issuance costs, and a debt facility with Merrill Lynch which provided financing of $7.8 million. Additionally, repayments on lines of credit totaled $2.6 million during the period.

The major financing activity in 2005 was the private placement of common stock, which provided $25.8 million net of issuance costs. Additionally, repayments on lines of credit totaled $1.0 million during the period.

Net cash provided by financing activities in 2004 was $0.2 million. The major financing activities included loan draws of $1.4 million for equipment financing in connection with the fit-out of our new corporate, research and development facility and repayments of $1.2 million on our existing borrowings.

Borrowings

We are a party to credit facilities with an aggregate outstanding amount of $7.0 million, including a $12 million senior secured credit facility with Merrill Lynch Capital of which $8.0 million has been drawn, and a loan agreement with a local government development fund, as described in the following table:

Debt Obligations	Interest Rates	Outstanding	Available
Montgomery County development loan	Fixed rate — 5%	$ 75,000	$—
Merrill Lynch Capital term loan	Variable rate — LIBOR plus 5%	6,889,000	—
Merrill Lynch Capital revolving loan	Variable rate — LIBOR plus 3.75%	—	—
Totals		$6,964,000	$—

The $12 million senior secured credit facility with Merrill Lynch Capital consists of an $8 million term loan and a $4 million revolving loan facility. We used the proceeds from the credit facility to repay existing indebtedness to M&T Bank of approximately $1 million, and anticipate using the remaining proceeds for general corporate purposes.

The $8 million Term Loan was drawn in its entirety at closing on June 30, 2006, and carries a maturity of three years, with equal monthly payments of principal. This loan is classified as a current liability due to the existence of a subjective acceleration clause which could, under certain circumstances, require the entire amount outstanding to be repaid within one year. Interest on the outstanding balance of the Term Loan is payable monthly at an annual rate equal to the one month LIBOR rate plus 5 percent. We issued no stock warrants or other dilutive securities in conjunction with the creation of the credit facility, and expect to repay the loan with cash flow from operations or from additional financing.

The Revolving Loan provides for an additional $4 million in potential borrowing capacity, subject to a borrowing base calculation based on eligible accounts receivable. It has a maturity of 45 months from closing, with an interest rate equal to the one month LIBOR plus 3.75 percent. The revolving loan facility is unused at December 31, 2006, as we have no available borrowing base capacity.

Pursuant to the credit and security agreement, we granted a security interest in substantially all of our assets existing at the date of closing as well as those acquired during the term of the agreement, to Merrill Lynch Capital, excluding intellectual property, which is subject to a negative pledge under which the Company has agreed not to grant a security interest in its intellectual property, as defined, without the consent of Merrill Lynch Capital. The agreement does not require the issuance of stock warrants or other equity types of securities.

The agreement restricts our ability to incur additional debt, pay dividends, repurchase stock, or engage in specified other transactions outside the normal course of business, as long as borrowings are outstanding under the agreement. The credit and security agreement also requires us to be in compliance with certain financial covenants, including achievement of a minimum quarterly amount of revenue/invoiced products and maintenance of a minimum liquidity level. On December 8, 2006, the agreement was amended to remove the financial covenant for revenue/invoiced products for the quarters ending December 31, 2006 and March 31, 2007. Beginning with the quarter ending June 30, 2007 and continuing thereafter, the financial covenant for minimum quarterly revenue is $5,000,000, an amount which significantly exceeds quarterly revenue recorded by us in prior periods and which requires the successful commercialization and market acceptance of our Keflex 750 mg product. In addition, the agreement contains a material adverse change clause under which the lender could accelerate the our obligations under the credit and security agreement upon either (1) the occurrence of an event that could reasonably be expected to result in a material adverse change, or (2) if the lender determines, in its good faith opinion, that there is a reasonable likelihood that we will fail to comply with one or more of the financial covenants during the succeeding financial reporting period. Due to the subjective acceleration clause, the entire outstanding balance of the term loan is classified as a current liability, pursuant to FASB Technical Bulletin 79-3, *"Subjective Acceleration Clauses in Long-Term Debt Agreements."*

We do not currently hedge any borrowings.

Stock Issuances

In December 2006, we completed a private placement of 6,000,000 shares of our common stock at a price of $3.00 per share, resulting in net proceeds after commissions and expenses of $16.7 million. There were no warrants associated with the transaction.

In April 2005, we completed a private placement of 6,846,735 shares of our common stock at a price of $3.98 per share and warrants to purchase a total of 2,396,357 shares of common stock at an exercise price of $4.78 per share, resulting in net proceeds, after commissions and expenses, of $25.8 million. The warrants are exercisable for five years.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2006 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

Payments Due by Period

Contractual Obligations (1), (2)	Total	2007	2008	2009	2010	2010	After 2011
				(In thousands)			
Short and long-term debt (includes interest)(3)	$ 7,913	$3,328	$2,976	$1,609	$ —	$ —	$ —
Minimum purchase commitments(4)	3,143	3,143	—	—	—	—	—
Operating lease obligations	13,906	2,079	2,139	2,156	2,214	2,155	3,163
Total contractual cash obligations	$24,962	$8,550	$5,115	$3,765	$2,214	$2,155	$3,163
Other commercial commitments(5)	$13,009	$9,680	$3,329	$ —	$ —	$ —	$ —

(1) This table does not include potential royalty payments, at a rate of 10% of sales value, to Eli Lilly and Company, which may be due on product line extensions of Keflex, including Keflex 750 mg. Any such royalties cannot be estimated at this time.

(2) This table does not include a contingent liability to Par Pharmaceutical under our amoxicillin development and commercialization agreement that was terminated by Par in August 2005. Under certain circumstances, the termination clauses of the agreement may entitle Par to receive a share of future net profits, if any, up to one-half of Par's total $23.25 million investment in the development of certain amoxicillin PULSYS products, should a product covered by the agreement be successfully commercialized. Accordingly, we retained $11.625 million of deferred revenue in recognition of this contingent liability to Par.

(3) Future interest obligation estimated based on interest rate in effect at year end of 10.35%.

(4) In the event we were to terminate our Innovex sales contract, we would incur minimum costs to exit of approximately $1.9 million. The remaining purchase commitments include costs of our product manufacturing capability under development in Ireland and Puerto Rico.

(5) We have entered into other contractual agreements in connection with developing our products and technology and to Innovex, a third party contract sales organization. These amounts represent the remaining contractual amount due over the remaining Innovex contract term, for on on-going commercialization efforts related to Amoxicillin PULSYS, and for manufacturing and research related to our Keflex product line.

In addition to the contractual obligations in the above table, we may incur funding liabilities for obligations which we enter into on a discretionary basis. These discretionary obligations could include additional facilities or equipment, investments in new technologies or products, acquisitions, funding of clinical trials, or similar events. Due to the success of our Amoxicillin Phase III trial in August 2006, we authorized the re-start of pre-production development work at the Clonmel facility, to prepare for commercial production of Amoxicillin PULSYS. In 2007, we expect to expend approximately $4.6 million in additional costs for development work at Clonmel.

During 2006 we spent approximately $0.1 million for capital expenditures, primarily for equipment purchased for use in our research and development facility in Germantown, Maryland.

Off-Balance Sheet Arrangements

We have not entered into any transactions, agreements or other contractual arrangements that meet the definition of off-balance sheet arrangements, with the exception of our private placement of common stock and warrants in April 2005. Warrants are instruments that meet the definition of a derivative under SFAS 133, although they qualify for the scope exception under paragraph 11 of SFAS 133. In the private placement, warrants were issued to purchase a total of 2,396,357 shares of common stock at an exercise price of $4.78 per share.

Prospective Information — Risks and Uncertainties related to Our Future Capital Requirements

At December 31, 2006, unrestricted cash, cash equivalents and marketable securities were $15.4 million compared to $29.4 million at December 31, 2005. We expect to incur a loss from operations in 2007. We believe that our existing cash resources will not be sufficient to fund our operations for 2007 even at reduced levels of research, development, sales and marketing activities. Thus, execution of our current strategies will require us to raise additional capital in order to finance our operations into early 2008. In order to minimize our financing requirements, we have initiated cost reductions including personnel reductions, postponement of PULSYS clinical development programs, and elimination of other discretionary spending We believe that additional financing may be available to us, but there can be no guarantee financing will be available on acceptable terms or at all.

We are evaluating various strategic alternatives to further enhance shareholder value, and in March 2007 we retained an investment banking firm to assist us in this regard. Strategic alternatives we may pursue could include, but are not limited to, continued execution of our operating plan, licensing or development arrangements, the sale of some or all of our company's assets, partnering or other collaboration agreements, or a merger or other strategic transaction. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

We have experienced significant losses since our inception in 2000, including a net loss of $42.0 million in 2006. As of December 31, 2006, we had an accumulated deficit of $153.1 million. The process of developing and commercializing our products requires significant research and development work, preclinical testing and clinical trials, as well as regulatory approvals, significant marketing and sales efforts, and manufacturing capabilities. These activities, together with our general and administrative expenses, are expected to continue to result in significant operating losses for the foreseeable future. To date, the revenues we have recognized from our non-PULSYS products have been limited and have not been sufficient for us to achieve or sustain profitability. Our product revenues are unpredictable in the near term and may fluctuate due to many factors, many of which we cannot control, including the market acceptance of our products. If our products fail to achieve market acceptance, we would have lower product revenues which may increase our capital requirements. If we fail to meet the minimum levels of revenue or liquidity (cash and marketable securities of $5 million) required by a financial covenant in the Merrill Lynch Capital term loan agreement, we could be required to repay the term loan on an accelerated basis, and we would experience significant liquidity issues.

Our cash and marketable securities on hand as of February 28, 2007 are approximately $7 million. We will need to raise capital in order to fund our future operations. Our net cash requirements in 2007 will depend, among other things, on the cash received from sales of our existing non-PULSYS products (primarily sales of Keflex capsules in 250mg, 500mg and 750mg strengths) and the cash expended for (1) cost of products sold, including royalties due to Eli Lilly on Keflex 750 net revenues, (2) research and development spending, (3) sales and marketing expenses for Keflex 750, and (4) general and administrative costs. We anticipate that our Keflex product sales will increase significantly in 2007 compared to 2006, because (a) 2006 included only approximately five months of product sales, (b) the growth we have observed in reported monthly prescriptions dispensed at pharmacies of Keflex 750 from August 2006 to February 2007 suggests that orders to us from wholesalers will also increase assuming monthly growth in prescriptions continues, and (c) price increases are planned to take effect in 2007. Our research and development expenditures are expected to decrease significantly in 2007 compared to 2006, as we have postponed all PULSYS development programs other than Amoxicillin PULSYS for adults, in

order to conserve financial resources. However, we plan to complete our development activities at the Clonmel, Ireland site, due to requirements of the anticipated FDA inspection activities at the site related to our Amoxicillin PULSYS New Drug Application. Our sales and marketing expenses for Keflex 750 are expected to increase in 2007 compared to 2006, as the 2006 expense was incurred for approximately a six-month period. We currently plan to maintain the contract sales force throughout 2007 to sell Keflex 750, although restructuring activities are planned to improve overall effectiveness and reduce costs, including expenses related to marketing. General and administrative expenses are expected to decrease due to planned reductions in personnel costs and in discretionary spending. We expect to incur a loss in 2007, as we expect that revenues from product sales will not be sufficient to fully fund our operating costs. These 2007 estimates are forward-looking statements that involve risks and uncertainties, and actual results could vary.

Our estimates of future capital requirements are uncertain and will depend on a number of factors, including the progress of our research and development of product candidates, the timing and outcome of regulatory approvals, cash received from sales of our existing non-PULSYS products, payments received or made under any future collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the acquisition of licenses for new products or compounds, the status of competitive products, the availability of financing and our or our partners' success in developing markets for our product candidates. Changes in our commercialization plans, partnering activities, regulatory activities and other developments may increase our rate of spending and decrease the period of time our available resources will fund our operations. Insufficient funds may require us to delay, scale back or eliminate some or all of our research, development or commercialization programs, or may adversely affect our ability to operate as a going concern.

We have no unused credit facility, other than the potential borrowing capacity under the Merrill Lynch revolving loan commitment of $4 million, or other committed sources of capital. We currently have no borrowing capacity under the revolving loan facility, and there can be no assurance that we will have borrowing capacity available under the Merrill Lynch Capital revolving loan in the future, as the borrowing base calculations are dependent on future levels of our eligible accounts receivable and availability of the revolving loan is dependent on the occurrence of no events of default. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to raise additional capital, incur indebtedness, or consider the sale of company assets in order to fund our operations. We are currently considering additional sources of capital, such as issuance of our stock. Additional debt financing is limited under the terms of our existing debt agreement with Merrill Lynch, and, in the absence of a waiver, we may need to repay the Merrill Lynch term loan as part of any new debt transaction. While we believe several financing alternatives may be available, there is no assurance additional debt or equity financing will be available on acceptable terms, if at all, or can be completed on a timely basis. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts, effect changes to our facilities or personnel, or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently. Any future funding may dilute the ownership of our equity investors.

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995

Certain statements contained in "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements are based on our current intent, belief and expectations. These statements are not guarantees of future performance and are subject to certain risks and uncertainties that are difficult to predict. Actual results may differ materially from these forward-looking statements because of our unproven business model, our dependence on new technologies, the uncertainty and timing of clinical trials, our ability to develop and commercialize products, our dependence on collaborators for services and revenue, our substantial indebtedness and lease obligations, our changing requirements and costs associated with planned facilities, intense competition, the uncertainty of patent and intellectual property protection, our dependence on key management and key suppliers, the uncertainty of regulation of products, the impact of future alliances or transactions and other risks

described in this filing and our other filings with the Securities and Exchange Commission. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today's date. We undertake no obligation to update or revise the information contained in this announcement whether as a result of new information, future events or circumstances or otherwise.

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

Our exposure to market risk is currently confined to our cash and cash equivalents, marketable securities, and restricted cash that generally have maturities of less than one year. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash, cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments, but may increase the interest expense associated with our debt.

Our most liquid assets are cash, cash equivalents and marketable securities. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our intellectual property. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our balance sheet. Due to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

Item 8. *Financial Statements and Supplementary Data*

The information required by this item is set forth on pages F-1 to F-32.

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

None.

Item 9A. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive and principal financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2006. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in this annual report on Form 10-K has been appropriately recorded, processed, summarized and reported. Based on that evaluation, our principal executive and principal financial officers have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting during the Quarter

Our management, including our principal executive and principal financial officers, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2006, and has concluded that there was no change that occurred during the quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Controls over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal controls over financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's system of internal controls over financial reporting was designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management, including the chief executive officer and chief financial officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2006. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework.* Based on our assessment, management concluded that the Company maintained effective internal control over financial reporting as of December 31, 2006.

The Company's independent registered public accounting firm has issued an audit report on management's assessment of the Company's internal control over financial reporting. Their report appears on page F-2 and F-3.

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

None.

PART III

Item 10. *Directors and Executive Officers of the Registrant*

We incorporate herein by reference the information concerning directors and executive officers in our Notice of Annual Stockholders' Meeting and Proxy Statement to be filed within 120 days after the end of our fiscal year (the "2007 Proxy Statement").

Item 11. *Executive Compensation*

We incorporate herein by reference the information concerning executive compensation to be contained in the 2007 Proxy Statement.

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

We incorporate herein by reference the information concerning security ownership of certain beneficial owners and management to be contained in the 2007 Proxy Statement.

Item 13. *Certain Relationships and Related Transactions*

We incorporate herein by reference the information concerning certain relationships and related transactions to be contained in the 2007 Proxy Statement.

Item 14. *Principal Accountant Fees and Services*

We incorporate herein by reference the information concerning certain relationships and related transactions to be contained in the 2007 Proxy Statement.

PART IV

Item 15. *Exhibits, Financial Statements Schedules and Reports on Form 8-K*

(a) The following documents are filed as part of this Annual Report:

(1) Index to Financial Statements

(2) Financial Statement Schedule

The following schedule is filed as part of this Form 10-K:

Exhibit II — Valuation and Qualifying Accounts for the Years Ended December 31, 2006, 2005, and 2004

(3) Exhibits

Exhibit No.	
2.1[(1) †+]	Asset Purchase Agreement dated as of June 30, 2004, by and between the Registrant and Eli Lilly and Company
3.1[(2)]	Certificate of Incorporation
3.2[(2)]	Bylaws
4.1[(2)]	Specimen Stock Certificate
10.1[(2)]	Executive Employment Agreement between the Registrant and Edward M. Rudnic dated January 7, 2000
10.2[(2)]	Executive Employment Agreement between the Registrant and Sandra E. Wassink dated August 13, 2003
10.3[(2)]	Executive Employment Agreement between the Registrant and Beth A. Burnside dated August 13, 2003
10.4[(2)]	Executive Employment Agreement between the Registrant and Darren Buchwald dated September 1, 2003
10.5[(3)]	Executive Employment Agreement between the Registrant and Donald Treacy dated March 19, 2004
10.6[(10)]	Executive Employment Agreement between the Registrant and Robert C. Low, dated December 12, 2005.
10.7[(2)]	Form of Indemnification Agreement
10.8[(4)]	Stock Incentive Plan
10.9[(2)]	Form of Incentive Stock Option Agreement
10.10[(2)]	Form of Non-qualified Stock Option Agreement
10.11[(2)]	Form of Stock Restriction Agreement
10.12[(5)]	Employee Stock Purchase Plan
10.13[(2)]	Form of Employment Agreement on Ideas, Inventions and Confidential Information
10.14[(2)]	Construction Services Agreement between the Registrant and Barclay White Skanska, Inc. dated July 12, 2002
10.15[(2)]	Amendment No. 1 dated April 7, 2003 to Agreement between Owner and Construction Manager dated July 12, 2002 between the Registrant and Skanska USA Building, Inc. successor by merger to Barclay White Skanska, Inc.
10.16[(2)]	Standard Form of Agreement between Owner and Architect with Standard Form of Architect's Services between the Registrant and Gaudreau, Inc. dated July 8, 2002
10.17[(2)]	Lease Agreement between the Registrant and Seneca Meadows Corporate Center II LLC dated August 1, 2002
10.18[(2)]	Stock Purchase Pledge Agreement between the Registrant and Edward M. Rudnic dated October 15, 2001
10.19[(2)]	Form of Stock Purchase Promissory Note by Edward M. Rudnic dated October 15, 2001
10.20[(2)]	Amendment dated June 12, 2002 to Stock Purchase Pledge Agreement dated October 15, 2001 between the Registrant and Edward M. Rudnic
10.21[(2)]	Amendment dated July 30, 2003 to the Stock Purchase Pledge Agreement and Stock Restriction Agreement dated October 15, 2001, as amended, between the Registrant and Edward M. Rudnic
10.22[(2)]	Note Issuance Agreement between the Registrant and HealthCare Ventures VI, L.P., Rho Management Trust, I, Steven Ostrofsky, Private Equity Holdings L.L.C., Targeted Entrepreneurial Services, LLC and the DC 1998 NFA Trust FBO Lee Casty dated March 28, 2003
10.23[(2)]	Form of Convertible Promissory Note dated March 28, 2003
10.24[(2)]	Amendment to Secured Convertible Promissory Note dated June 23, 2003
10.25[(2)]	Fourth Amended and Restated Stockholders' Agreement
10.26[(2)]	Omnibus Addendum and Amendment to Series E Convertible Preferred Stock Purchase Agreement and Fourth Amended and Restated Stockholders' Agreement
10.27[(2)]	Consulting Agreement dated August 18, 2000 between the Registrant and Jenefir Isbister as amended

Exhibit No.	
10.28[2]	Credit Agreement between the Registrant and Manufacturers and Traders Trust Company dated July 31, 2003
10.29[2]	Specific Security Agreement between the Registrant and Manufacturers and Traders Trust Company dated July 31, 2003
10.30[2] +	Development and License Agreement between the Registrant and GlaxoSmithKline dated July 18, 2003
10.31[2] +	Supply, Distribution and Marketing Agreement between the Registrant and Par Pharmaceutical, Inc. dated September 4, 2003
10.32[2] +	Manufacturing Agreement dated as of June 30, 2004, by and between the Registrant and Eli Lilly and Company
10.33[2] +	Transition Services Agreement dated as of June 30, 2004, by and between the Registrant and Eli Lilly and Company
10.34[5] +	Development and Commercialization Agreement between the Registrant and Par Pharmaceutical, Inc. dated May 28, 2004
10.35[6] +	Commercial Supply Agreement between the Registrant and Ceph International Corporation dated December 3, 2004
10.36[6] +	First Amendment to Development and Commercialization Agreement between the Registrant and Par Pharmaceutical Corporation dated December 14, 2004
10.37[7] +	Manufacturing and Supply Agreement between the Registrant and Clonmel Healthcare Limited, dated as of April 19, 2005.*
10.38[7] +	Development and Clinical Manufacturing Agreement between the Registrant and Clonmel Healthcare Limited, dated as of April 19, 2005.*
10.39[7] +	Facility Build-Out Agreement between the Registrant and Clonmel Healthcare Limited, dated as of April 19, 2005.*
10.40[8] +	Form of Purchase Agreement dated April 26, 2005, including the form of Warrant attached thereto.**
10.41[9]	Credit and Security Agreement, dated June 30, 2006 between the Registrant and Merrill Lynch Capital.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1	Rule 13a-14(a) Certification of Principal Executive Officer.
31.2	Rule 13a-14(a) Certification of Principal Financial Officer.
32.1	Section 1350 Certification of Chief Executive Officer.
32.2	Section 1350 Certification of Chief Financial Officer.

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[1] Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-107599).

[2] Incorporated by reference to our Registration Statement on Form S-8 (File No. 333-109728).

[3] Incorporated by reference to our Quarterly Report on Form 10-Q filed May 7, 2004.

[4] Incorporated by reference to our Current Report on Form 8-K filed July 15, 2004.

[5] Incorporated by reference to our Quarterly Report on Form 10-Q filed August 6, 2004

[6] Incorporated by reference to our Quarterly Report on Form 10-Q filed November 5, 2004

[7] Incorporated by reference to our Quarterly Report on Form 10-Q filed August 15, 2005.

[8] Incorporated by reference to our Current Report on Form 8-K filed April 27, 2005.

[9] Incorporated by reference to our Quarterly Report on Form 10-Q filed August 9, 2006.

[10] Incorporated by reference to our Current Report on Form 8-K filed December 16, 2005.

† The Schedules and certain of the Exhibits to this Asset Purchase Agreement have been omitted in reliance upon the rules of the Securities and Exchange Commission. A copy will be delivered to the Securities and Exchange Commission upon request.

+ Confidential treatment requested for certain portions of this Exhibit pursuant to Rule 406 under the Securities Act, which portions are omitted and filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ADVANCIS PHARMACEUTICAL CORPORATION

By: /s/ EDWARD M. RUDNIC
Edward M. Rudnic, Ph.D.
President and Chief Executive Officer

Dated: March 26, 2007

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

Signature	Title	Date
/s/ R. GORDON DOUGLAS R. Gordon Douglas, M.D.	Chairman of the Board of Directors	March 26, 2007
/s/ EDWARD M. RUDNIC Edward M. Rudnic, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2007
/s/ ROBERT C. LOW Robert C. Low	Vice President — Finance, Chief Financial Officer, and Treasurer (Principal Financial and Accounting Officer)	March 26, 2007
/s/ JAMES H. CAVANAUGH James H. Cavanaugh, Ph.D.	Director	March 26, 2007
/s/ RICHARD W. DUGAN Richard W. Dugan	Director	March 26, 2007
/s/ WAYNE T. HOCKMEYER Wayne T. Hockmeyer, Ph.D.	Director	March 26, 2007
/s/ HAROLD R. WERNER Harold R. Werner	Director	March 26, 2007

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders
of Advancis Pharmaceutical Corporation:

We have completed integrated audits of Advancis Pharmaceutical Corporation's financial statements and of its internal control over financial reporting as of December 31, 2006, in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Financial statements and financial statement schedule

In our opinion, the financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of Advancis Pharmaceutical Corporation at December 31, 2006 and December 31, 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements 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.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has insufficient liquidity to fund its ongoing operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 2 to the financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006.

Internal control over financial reporting

Also, in our opinion, management's assessment, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2006 based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control — Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland
March 23, 2007

ADVANCIS PHARMACEUTICAL CORPORATION

BALANCE SHEETS

	December 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,856,738	$ 18,116,968
Marketable securities	522,723	11,314,090
Restricted cash	—	418,244
Accounts receivable, net	303,514	756,764
Notes receivable from officer	—	121,500
Inventories, net	2,077,390	219,451
Prepaid expenses and other current assets	1,682,685	797,253
Total current assets	19,443,050	31,744,270
Property and equipment, net	11,764,627	14,450,627
Restricted cash	872,180	1,182,680
Deposits and other assets	1,548,585	884,312
Intangible assets, net	8,377,327	9,535,003
Total assets	$ 42,005,769	$ 57,796,892
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,285,736	$ 1,686,487
Accrued expenses and advances	7,817,224	7,071,731
Lines of credit and short term debt	6,888,889	895,204
Note payable	75,000	—
Deferred product revenue	189,000	—
Total current liabilities	17,255,849	9,653,422
Lines of credit — noncurrent portion	—	597,208
Note payable	—	75,000
Accrued severance — noncurrent portion	—	1,235,394
Deferred contract revenue	11,625,000	11,625,000
Deferred rent and credit on lease concession	1,252,900	1,268,857
Total liabilities	30,133,749	24,454,881
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized, no shares issued or outstanding at December 31, 2006 and 2005	—	—
Common stock, $0.01 par value; 225,000,000 shares authorized, and 36,362,447 and 29,765,139 shares issued and outstanding at December 31, 2006 and 2005, respectively	363,625	297,652
Capital in excess of par value	164,593,930	144,766,213
Deferred stock-based compensation	—	(623,051)
Accumulated deficit	(153,085,462)	(111,095,308)
Accumulated other comprehensive loss	(73)	(3,495)
Total stockholders' equity	11,872,020	33,342,011
Total liabilities and stockholders' equity	$ 42,005,769	$ 57,796,892

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

ADVANCIS PHARMACEUTICAL CORPORATION

STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2006	2005	2004
Revenues:			
Product sales	$ 4,810,410	$ 4,809,222	$ 2,396,500
Contract revenue	—	4,027,778	5,347,223
Reimbursement of development costs	—	8,010,690	3,614,309
Total revenue	4,810,410	16,847,690	11,358,032
Cost and expenses:			
Cost of product sales	899,601	562,009	169,854
Research and development	25,973,844	39,729,441	33,642,930
Selling, general and administrative	21,288,968	10,515,302	12,219,409
Total expenses	48,162,413	50,806,752	46,032,193
Loss from operations	(43,352,003)	(33,959,062)	(34,674,161)
Interest income	895,685	1,075,084	793,818
Interest expense	(510,651)	(120,891)	(124,370)
Other income	976,815	16,292	—
Net loss	$(41,990,154)	$(32,988,577)	$(34,004,713)
Basic and diluted net loss per share applicable to common stockholders	$ (1.38)	$ (1.20)	$ (1.50)
Shares used in calculation of basic and diluted net loss per share	30,535,965	27,421,516	22,684,410

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

ADVANCIS PHARMACEUTICAL CORPORATION

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Common Shares	Par Value	Capital in Excess of Par Value	Deferred Stock-Based Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
Balance at December 31, 2003	22,639,344	$226,394	$120,141,450	$(6,126,286)	$ (44,102,018)	$ 10,380	$ 70,149,920
Exercise of stock options	26,764	268	15,976	—	—	—	16,244
Issuance of restricted stock	40,571	405	24,305	—	—	—	24,710
Issuance and remeasurement of stock options for services	—	—	26,370	—	—	—	26,370
Stock-based compensation for retired director	—	—	416,141	73,810	—		489,951
Amortization of deferred stock-based compensation	—	—	—	3,296,898	—	—	3,296,898
Reversal of deferred stock-based compensation and related amortization due to forfeited options	—	—	(308,293)	148,331	—	—	(159,962)
Comprehensive income (loss):							
Net loss	—	—	—	—	(34,004,713)	—	(34,004,713)
Unrealized loss on marketable securities, net	—	—	—	—	—	(101,039)	(101,039)
Total comprehensive loss							(34,105,752)
Balance at December 31, 2004	22,706,679	227,067	120,315,949	(2,607,247)	(78,106,731)	(90,659)	39,738,379
Exercise of stock options	171,155	1,712	98,783	—	—	—	100,495
Issuance of restricted stock	40,570	406	24,305	—	—	—	24,711
Issuance and remeasurement of stock options for services	—	—	(123,149)	—	—	—	(123,149)
Amortization of deferred stock-based compensation	—	—	—	1,522,554	—	—	1,522,554
Reversal of deferred stock-based compensation and related amortization due to forfeited options	—	—	(1,325,261)	461,642	—	—	(863,619)
Proceeds from private placement of common stock and warrants, net of issuance expenses	6,846,735	68,467	25,775,586	—	—	—	25,844,053
Comprehensive income (loss):							
Net loss	—	—	—	—	(32,988,577)	—	(32,988,577)
Unrealized gain on marketable securities, net	—	—	—	—	—	87,164	87,164
Total comprehensive loss							(32,901,413)
Balance at December 31, 2005	29,765,139	297,652	144,766,213	(623,051)	(111,095,308)	(3,495)	33,342,011
Exercise of stock options	558,377	5,584	347,153	—	—	—	352,737
Issuance of restricted stock	38,931	389	23,748	—	—	—	24,137
Issuance and remeasurement of stock options for services	—	—	323,273	—	—	—	323,273
Stock-based employee compensation expense	—	—	3,080,790	—	—	—	3,080,790
Elimination of deferred stock-based compensation due to adoption of SFAS 123R	—	—	(623,051)	623,051	—	—	—
Proceeds from private placement of common stock, net of issuance expenses	6,000,000	60,000	16,675,804	—	—	—	16,735,804
Comprehensive income (loss):							
Net loss	—	—	—	—	(41,990,154)	—	(41,990,154)
Unrealized gain on marketable securities, net	—	—	—	—	—	3,422	3,422
Total comprehensive loss							(41,986,732)
Balance at December 31, 2006	36,362,447	$363,625	$164,593,930	$ —	$(153,085,462)	$ (73)	$ 11,872,020

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

ADVANCIS PHARMACEUTICAL CORPORATION

STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2006	2005	2004
Cash flows from operating activities:			
Net loss	$(41,990,154)	$(32,988,577)	$(34,004,713)
Adjustments to reconcile net income to net cash used in operating activities:			
Depreciation and amortization	3,919,267	4,044,419	2,714,341
Stock-based compensation	3,404,063	535,786	3,653,257
Deferred rent and credit on lease concession	(15,957)	47,629	453,469
Amortization of premium on marketable securities	204,525	253,483	1,297,947
(Gain) or loss on disposal of fixed assets	23,185	(16,292)	—
Recognition of advance payment for potential sale of Keflex	(1,000,000)	—	—
Changes in:			
Accounts and notes receivable	574,751	(406,648)	2,649,884
Inventories	(1,857,939)	(39,713)	(179,738)
Prepaid expenses and other current assets	(885,432)	247,136	83,075
Deposits other than on property and equipment, and other assets	(30,096)	(62,394)	(49,142)
Accounts payable	599,249	(2,200,076)	1,202,850
Accrued expenses and advances	534,236	3,483,910	1,653,637
Deferred product and contract revenue	189,000	2,211,532	5,038,468
Net cash used in operating activities	(36,331,302)	(24,889,805)	(15,486,665)
Cash flows from investing activities:			
Purchase of Keflex intangible assets	—	—	(11,205,517)
Advance payment for potential sale of Keflex intangible assets	—	1,000,000	—
Purchase of marketable securities	(13,764,736)	(15,029,229)	(25,918,898)
Sale and maturities of marketable securities	24,355,000	23,205,000	32,500,364
Purchases of property and equipment	(61,296)	(1,365,088)	(6,200,677)
Deposits on property and equipment	(489,633)	(557,793)	(759,638)
Proceeds from sale of fixed assets	25,000	111,163	—
Change in restricted cash	728,744	312,390	(136,745)
Net cash provided by (used in) investing activities	10,793,079	7,676,443	(11,721,111)
Cash flows from financing activities:			
Proceeds from lines of credit	—	—	1,389,396
Proceeds from issuance of debt, net of issue costs	7,792,976	—	—
Payments on lines of credit	(2,603,524)	(1,009,975)	(1,252,597)
Proceeds from private placement of common stock, net of issuance costs	16,735,804	25,844,053	—
Proceeds from exercise of common stock options	352,737	100,495	16,244
Net cash provided by financing activities	22,277,993	24,934,573	153,043
Net increase (decrease) in cash and cash equivalents	(3,260,230)	7,721,211	(27,054,733)
Cash and cash equivalents, beginning of period	18,116,968	10,395,757	37,450,490
Cash and cash equivalents, end of period	$ 14,856,738	$ 18,116,968	$ 10,395,757
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 386,454	$ 120,891	$ 127,094
Supplemental disclosure of non-cash transactions:			
Reclassification of liability related to early exercises of restricted stock to equity upon vesting of the restricted stock	$ 24,137	$ 24,711	$ 24,710
Equipment and construction costs in accrued liabilities	$ —	$ —	$ 457,189

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

1. Nature of the Business

Advancis Pharmaceutical Corporation (the "Company") was incorporated in Delaware in December 1999 and commenced operations on January 1, 2000. The Company is focused on developing and commercializing anti-infective drug products that fulfill unmet medical needs in the treatment of infectious disease. The Company is developing a portfolio of drugs based on the novel biological finding that bacteria exposed to antibiotics in front-loaded, sequential bursts, or pulses, are killed more efficiently than those exposed to standard antibiotic treatment regimens. The Company has initially focused on developing pulsatile formulations of approved and marketed drugs that no longer have patent protection or that have patents expiring in the next several years. In 2004, the Company acquired the U.S. rights to Keflex (cephalexin capsules, USP) from Eli Lilly and commenced product sales.

The Company has experienced significant operating losses since its inception in 2000, including a net loss of $42.0 million in 2006. As of December 31, 2006, the Company had an accumulated deficit of $153.1 million. The process of developing and commercializing the Company's products requires significant research and development work, preclinical testing and clinical trials, as well as regulatory approvals, significant marketing and sales efforts, and manufacturing capabilities. These activities, together with the Company's general and administrative expenses, require significant investments and are expected to continue to result in significant operating losses for the foreseeable future. In August 2006, the Company successfully completed a Phase III clinical trial for its lead product candidate, Amoxicillin PULSYS, and it expects to incur significant expenses in preparing for the commercial launch of the product, anticipated as soon as in early 2008. To date, revenues recognized from non-PULSYS products have been limited and have not been sufficient for the Company to achieve or sustain profitability. The Company expects to incur a loss from operations in 2007. The Company believes it is unlikely that its existing cash resources will be sufficient to fund its operations for 2007 at its planned levels of research, development, sales and marketing activities. Thus, execution of its current strategies will require it to raise additional capital through debt or equity transactions in order to finance its operations through 2007. The Company believes that additional financing may be available to it, but there can be no guarantee financing will be available on acceptable terms or at all. If adequate funds are not available, the Company may be required to delay, reduce the scope of or eliminate its research and development programs, reduce its commercialization efforts, or effect changes to its facilities or personnel, and its ability to operate as a going concern may be adversely impacted.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

Product sales revenue, net of estimated provisions, is recognized when persuasive evidence that an arrangement exists, delivery has occurred, the selling price is fixed or determinable, and collectibility is reasonably assured. Provisions for sales discounts, and estimates for chargebacks, rebates, and product returns are established as a reduction of product sales revenue at the time revenues are recognized, based on historical experience adjusted to reflect known changes in the factors that impact these reserves. These factors include current contract prices and terms, estimated wholesaler inventory levels, remaining shelf life of product, and historical information for similar products in the same distribution channel.

Contract revenues include license fees and milestone payments associated with collaborations with third parties. Revenue from non-refundable, upfront license fees where the Company has continuing involvement is recognized ratably over the development or agreement period.

Revenue for reimbursement of development costs is recognized as the actual costs to perform the work are incurred. Revenue recognized is limited to minimum amounts expected to be received under the specific agreements and excludes amounts contingent on future events, such as successful commercialization, and amounts that are contingently refundable.

Deferred product revenue represents goods shipped under guaranteed sale arrangements in connection with initial stocking for a new product launch. For such arrangements, the risk of loss has not passed to the customer, and, accordingly products delivered under guaranteed sale arrangements are accounted for as consignment sales. The Company recognizes revenue when the product is sold by its customer or at the expiration of the consignment period if the product has not been returned.

Deferred contract revenue represents cash received in excess of revenue recognized.

Research and Development

The Company expenses research and development costs as incurred. Research and development costs primarily consist of salaries and related expenses for personnel, fees paid to consultants and outside service providers, including clinical research organizations for the conduct of clinical trials, costs of materials used in clinical trials and research and development, development costs for contract manufacturing prior to FDA approval of products, depreciation of capital resources used to develop products, and costs of facilities, including costs to modify third-party facilities.

Cash and Cash Equivalents

Cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of time deposits, investments in money market funds with commercial banks and financial institutions, commercial paper and high-quality corporate bonds. At December 31, 2006 and 2005, the Company maintained all of its cash and cash equivalents in three financial institutions. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand, and the Company believes there is minimal risk of losses on such cash balances.

Restricted Cash

In conjunction with the lease of its corporate, research and development facilities, the Company provided the landlord with letters of credit that were collateralized with restricted cash deposits in the amounts of $872,180 at December 31, 2006, and $1,059,000 at December 31, 2005 (see Note 19). These deposits are recorded as non-current restricted cash at December 31, 2006 and 2005. The Company had established cash deposit accounts totaling $541,924 as of December 31, 2005, that were pledged as collateral for lines of credit (see Note 10). In 2006 the lines of credit were fully paid off, and the restriction on the deposit was released.

Marketable Securities

The Company classifies all of its marketable securities as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported as a component of stockholders' equity in accumulated other comprehensive loss. Marketable securities available for current operations are classified in the balance sheet as current assets; marketable securities held for long-term purposes are classified as noncurrent assets. Interest income, net of amortization of premium on marketable securities, and realized gains and losses on securities are included in "Interest income" in the statements of operations.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, marketable securities, notes payable and line of credit borrowings, approximate their fair values due to their short maturities.

Accounts Receivable

Accounts receivable represent amounts due from wholesalers for sales of pharmaceutical products. Allowances for estimated product discounts and chargebacks are recorded as reductions to gross accounts receivable. Amounts due for returns and estimated rebates payable to third parties are included in accrued liabilities.

Inventories

Inventories consist of finished products purchased from third-party contract manufacturers and are stated at the lower of cost or market. Cost is determined on the first-in, first-out (FIFO) method. Reserves for obsolete or slow-moving inventory are recorded as reductions to inventory cost. The Company periodically reviews its product inventories on hand. Inventory levels are evaluated by management relative to product demand, remaining shelf life, future marketing plans and other factors, and reserves for obsolete and slow-moving inventories are recorded for amounts which may not be realizable.

Property and Equipment

Property and equipment are stated at cost and depreciated over their estimated useful lives using the straight-line method. Leasehold improvements are capitalized and amortized over the shorter of their economic life or the lease term. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

Intangible Assets

Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives. The Keflex brand rights are amortized over 10 years, the Keflex non-compete agreement with Eli Lilly and Company is amortized over five years, and certain acquired patents are amortized over 10 years. The Company does not have identifiable intangible assets with indefinite lives. The Keflex brand name and other intangible assets were acquired for marketing purposes, and the related amortization is charged to selling expense.

Patents are carried at cost less accumulated amortization which is calculated on a straight-line basis over the estimated useful lives of the patents. The Company periodically reviews the carrying value of patents to determine whether the carrying amount of the patent is recoverable. For the years ended December 31, 2006, 2005 and 2004, there were no adjustments to the carrying values of patents. The Company is amortizing the cost of the patent applications over a period of 10 years. Ownership of all of its patents is retained by the Company in all of its transactions.

Impairment of Long-Lived Assets

SFAS No. 144, *"Accounting for the Impairment or Disposal of Long-Lived Assets,"* establishes accounting standards for the impairment of long-lived assets. The Company reviews its long-lived assets, including property and equipment and intangible assets, for impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. If this review indicates that the asset will not be recoverable based on the expected undiscounted net cash flows of the related asset, an impairment loss is recognized. There were no indicators of impairment through 2006, and consequently there were no impairment losses recognized in 2006, 2005, or 2004. If the Company is not able to obtain approval for its New Drug Application or carry out its business

plans, there is the potential that this will be an indicator of an event or change in circumstances under SFAS 144 that would require the Company to perform an impairment analysis, and ultimately may result in impairment of the long-lived assets.

Leases

The Company leases its office and laboratory facilities under operating leases. Lease agreements may contain provisions for rent holidays, rent escalation clauses or scheduled rent increases, and landlord lease concessions such as tenant improvement allowances. The effects of rent holidays and scheduled rent increases in an operating lease are recognized over the term of the lease, including the rent holiday period, so that rent expense is recognized on a straight-line basis. For lease concessions such as tenant improvement allowances, the Company records a deferred rent liability included in "Deferred rent and credit on lease concession" on the balance sheet and amortizes the deferred liability on a straight-line basis as a reduction to rent expense over the term of the lease. The tenant improvements are capitalized as leasehold improvements and are amortized over the shorter of the economic life of the improvement or the lease term (excluding optional renewal periods). Amortization of leasehold improvements is included in depreciation expense. The Company's leases do not include contingent rent provisions.

Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Comprehensive Income

SFAS No. 130, *"Reporting Comprehensive Income,"* requires a full set of general-purpose financial statements to include the reporting of "comprehensive income." Comprehensive income is composed of two components, net income and other comprehensive income. For the years ended December 31, 2006, 2005 and 2004, other comprehensive income (loss) of $3,422, $87,164 and $(101,039), respectively, consists of unrealized gains and losses on available-for-sale marketable securities.

Earnings Per Share

Basic earnings per share is computed based on the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed based on the weighted average shares outstanding adjusted for all dilutive potential common shares. The dilutive impact, if any, of potential common shares outstanding during the period, including outstanding stock options, is measured by the treasury stock method. Potential common shares are not included in the computation of diluted earnings per share if they are antidilutive. The Company incurred net losses for 2006, 2005 and 2004 and, accordingly, did not assume exercise of any of the Company's outstanding stock options, or warrants, because to do so would be antidilutive.

The following are the securities that could potentially dilute basic earnings per share in the future that were not included in the computation of diluted earnings per share because to do so would have been antidilutive for the periods presented:

(Number of Underlying Common Shares)	December 31, 2006	2005	2004
Stock options	4,378,578	4,095,417	3,736,726
Nonvested restricted stock	30,052	71,032	237,689
Warrants	2,396,357	2,396,357	—
Total	6,804,987	6,562,806	3,974,415

Segment and Geographic Information

In accordance with SFAS No. 131, *"Disclosure about Segments of an Enterprise and Related Information,"* the Company has determined that it operates in one business segment. The Company is organized along functional lines of responsibility and does not utilize a product, divisional or regional organizational structure. The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer.

The Company sells its products to a limited number of pharmaceutical wholesalers, and all product sales occur in the United States. Long-lived assets, consisting of property and equipment, are located both in the United States and Ireland.

Geographic Information	Product Sales	Long-Lived Assets
United States	$4,810,410	$10,551,686
Ireland	—	1,212,941
Total	$4,810,410	$11,764,627

Recent Accounting Pronouncements

Effective January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123R, *"Share-Based Payment,"* (SFAS 123R), a revision of SFAS 123, *"Accounting for Stock-based Compensation."* SFAS 123R requires companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use APB Opinion 25's intrinsic value method of accounting for share-based payments. The Company selected the modified prospective method of adoption. Under this method, compensation expense recognized by the Company for the twelve month period ended December 31, 2006 included: (a) compensation expense for all share-based payments granted prior to, but not vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation expense for all share-based payments granted on or after January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. Results for prior periods were not restated. See Notes 15 and 16 to the financial statements for more details on stock-based compensation.

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48 ("FIN 48"), *"Accounting for Uncertainty in Income Taxes."* The interpretation clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS 109, *"Accounting for Income Taxes."* It prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken on a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the impact, if any, of FIN 48 on its financial statements.

In September 2006, the FASB issued SFAS No. 157, *"Fair Value Measurements"* (SFAS 157), which provides guidance for how companies should measure fair value, when required to use a fair value measurement for recognition or disclosure purposes under generally accepted accounting principles. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the impact, if any, the adoption of SFAS 157 will have on its financial statements.

In December 2006, FASB Staff Position No. EITF 00-19-2, *"Accounting for Registration Payment Arrangements,"* was issued. The FSP specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with SFAS No. 5, *"Accounting for Contingencies."* The Company believes its current accounting is consistent with the FSP. Accordingly, adoption of the FSP had no effect on the financial statements.

In February 2007, the FASB issued SFAS No. 159, *"The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115"*, under which entities will now be permitted to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis. This Statement is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Early adoption is permitted as of the beginning of a fiscal year that begins on or before November 15, 2007, provided the entity also elects to apply the provisions of SFAS 157. The Company is currently assessing the impact, if any, the adoption of SFAS 159 will have on its financial statements.

3. Revenue

The Company records revenue from sales of pharmaceutical products (Keflex brand) and, in 2005 and 2004, from the recognition of revenue earned under collaboration agreements.

Product Sales. The Company's largest customers are large wholesalers of pharmaceutical products. Cardinal Health, McKesson, and AmerisourceBergen accounted for approximately 43.6%, 33.5%, and 13.8% of the Company's net revenues from product sales in the year ended December 31, 2006, and 59.7%, 20.9%, and 13.7% of the Company's net revenues from product sales in the year ended December 31, 2005, respectively.

Contract Revenue. Revenue recognized for upfront payments and milestones under collaboration agreements is as follows:

	December 31,		
Contract Revenue	**2006**	**2005**	**2004**
Upfront payment — GSK — amortization	$—	$ —	$1,145,833
Upfront payment — GSK — acceleration upon termination	—	—	3,229,167
Upfront payment — Par — amortization	—	796,783	972,223
Upfront payment — Par — acceleration upon termination	—	3,230,995	—
Total	$—	$4,027,778	$5,347,223

The GSK and Par collaborations have been terminated, and the Company currently has no other collaborations in place that would provide future funding or revenue.

Reimbursement of Development Costs. Revenue recognized for reimbursement by third parties of research and development costs is as follows:

	December 31,		
Reimbursement of Development Costs	**2006**	**2005**	**2004**
Reimbursement by Par of period costs incurred	$—	$5,635,690	$3,614,309
Acceleration upon termination of Par collaboration	—	2,375,000	—
Total	$—	$8,010,690	$3,614,309

6. Inventories

Inventories, net, consist of the following:

	December 31, 2006	December 31, 2005
Finished goods	$2,371,346	$ 373,818
Reserve for obsolete and slow-moving inventory	(293,956)	(154,367)
Inventories, net	$2,077,390	$ 219,451

The Company periodically reviews its product inventories on hand. Inventory levels are evaluated by management relative to product demand, remaining shelf life, future marketing plans and other factors, and reserves for obsolete and slow-moving inventories are recorded for amounts which may not be realizable. The Company recorded provisions for excess inventory of $140,000 and $154,367 in the years ended December 31, 2006 and 2005, respectively.

7. Prepaids and Other Current Assets

Prepaid expenses and other current assets consists of the following:

	December 31, 2006	December 31, 2005
Prepaid insurance	$ 804,790	$771,707
New Drug Application filing fee — refundable	672,150	—
Other prepaid costs	205,745	25,546
Prepaid expenses and other current assets	$1,682,685	$797,253

At December 31, 2006 prepaid expenses and other current assets included the refundable portion of a filing fee paid to the FDA for a New Drug Application (NDA) the Company submitted for Amoxicillin PULSYS in 2006. The total NDA filing fee paid was $896,200. The remaining $224,050 balance of the NDA fee paid, which was charged to general and administrative expense in 2006, is potentially refundable to the Company should the Company meet the requirements for a small business waiver. The Company's application for the waiver is currently under review by the FDA and Small Business Administration.

8. Property and Equipment

Property and equipment consist of the following:

	Estimated Useful Life (Years)	December 31, 2006	December 31, 2005
Construction in progress	n/a	$ 554,673	$ 535,463
Computer equipment	3	1,024,149	1,010,757
Furniture and fixtures	3-10	1,405,918	1,405,918
Equipment	3-10	9,140,957	9,197,693
Leasehold improvements	Shorter of economic lives or lease term	8,738,230	8,719,668
Subtotal		20,863,927	20,869,499
Less — accumulated depreciation		(9,099,300)	(6,418,872)
Property and equipment, net		$11,764,627	$14,450,627

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Reimbursement of Development Costs	**2006**	**2005**	**2004**
Reimbursement by Par of period costs incurred	$—	$5,635,690	$3,614,309
Acceleration upon termination of Par collaboration	—	2,375,000	—
Total	$—	$8,010,690	$3,614,309

Collaboration with GlaxoSmithKline (GSK). In July 2003, the Company entered into a development and license agreement with GSK pursuant to which the Company exclusively licensed patents and PULSYS technology to GSK for potential use on some of its products. In consideration for the licensing of its technology, the Company received an upfront payment of $5.0 million, which was being amortized over the expected development period. The Company recognized revenue of $1,145,833 in the year ended December 31, 2004 for the amortization of the $5,000,000 upfront payment based on the original development schedule of GSK. In 2004, GSK notified the Company that it would terminate this agreement, effective December 15, 2004. As a result, the remaining deferred revenue balance of $3,229,167 was recognized as revenue in the fourth quarter of 2004.

Collaboration with Par Pharmaceutical for Amoxicillin PULSYS. In May 2004, the Company entered into an agreement with Par Pharmaceutical to collaborate in the further development and commercialization of a PULSYS-based amoxicillin product. Under the terms of the agreement, the Company conducted the development program, including the manufacture of clinical supplies and the conduct of clinical trials, and was responsible for obtaining regulatory approval for the product. The Company was to own the product trademark and was to manufacture or arrange for supplies of the product for commercial sales. Par was to be the sole distributor of the product. Both parties were to share commercialization expenses, including pre-marketing costs and promotion costs, on an equal basis. Operating profits from sales of the product were also to be shared on an equal basis. Under the agreement, the Company received an upfront fee of $5,000,000 and a commitment from Par to fund all further development expenses. Development expenses incurred by the Company were to be partially funded by quarterly payments aggregating $28 million over the period of July 2004 through October 2005, of which up to $14 million would have been contingently refundable.

Revenue related to the receipt of the quarterly payments from Par was recognized based on actual costs incurred as the work was performed, limited to the minimum amounts expected to be received under the agreement and excluding amounts contingent on future events or that were contingently refundable, with the balance of cash received in excess of revenue recognized recorded as deferred revenue. The excess of the development costs incurred by the Company over the quarterly payments made by Par was to be funded subsequent to commercialization, by the distribution to the Company of Par's share of operating profits until the excess amount had been reimbursed. The Company did not record any amounts as revenue on a current basis that were dependent on achievement of future operating profits.

On August 3, 2005, the Company was notified by Par that Par decided to terminate the companies' Amoxicillin PULSYS collaboration agreement. Advancis received from Par the $4,750,000 development funding quarterly payment due in July 2005 and expects no further payments under the collaboration. Under certain circumstances, the termination clauses of the agreement may entitle Par to receive a share of net profits up to one-half of their cumulative $23,250,000 funding of the development costs of certain Amoxicillin PULSYS products, should a product covered by the agreement be successfully commercialized. Accordingly, in 2005 the Company retained deferred revenue of $11,625,000 related to the agreement, and accelerated the recognition into current revenue of the remaining balance of $2,375,000 of deferred reimbursement revenue.

Revenue related to the $5,000,000 upfront fee was being amortized into contract revenue on a straight-line basis over the estimated development period. As a result of the termination, the Company recognized the remaining deferred revenue balance of $3,230,995 related to the upfront fee as revenue in 2005.

4. Marketable Securities

Marketable securities, including accrued interest, at December 31, 2006 and 2005 were as follows:

	December 31, 2006			
Available-for-sale	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
Corporate debt securities:				
-In unrealized loss position under 12 months..	$522,796	$—	$(73)	$522,723

	December 31, 2005			
Available-for-sale	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
Corporate debt securities				
-In unrealized gain position	$ 1,988,491	$2,173	$ —	$ 1,990,664
-In unrealized loss position under 12 months	7,820,334	—	(3,095)	7,817,239
-In unrealized loss position over 12 months	1,508,760		(2,573)	1,506,187
	$11,317,585	$2,173	$(5,668)	$11,314,090

At December 31, 2006, there was one security in an unrealized loss position for less than 12 months, and no securities in an unrealized loss position for greater than 12 months. The unrealized loss on the Company's investment in a corporate debt security was caused by interest rate increases. The contractual term of this investment does not permit the issuer to settle the security at a price less than the amortized cost of the investment. Because the decline in market value is attributable to changes in interest rates and not credit quality, and because the Company has the ability and intent to hold this investment until a recovery of fair value, which may be maturity, the Company does not consider this investment to be other-than-temporarily impaired at December 31, 2006. In 2006, the Company did not experience any realized losses in its marketable securities portfolio.

Each of the Company's marketable securities at December 31, 2006 matures within six months.

5. Accounts Receivable

Accounts receivable, net, consists of the following:

	December 31, 2006	December 31, 2005
Accounts receivable for product sales, gross	$ 520,444	$1,109,684
Allowances for discounts and chargebacks	(216,930)	(352,920)
Accounts receivable for product sales, net	$ 303,514	$ 756,764

The Company's largest customers are large wholesalers of pharmaceutical products. Three of these large wholesalers accounted for approximately 48.9%, 24.0% and 18.3% of the Company's accounts receivable for product sales as of December 31, 2006, and 80.7%, 10.4%, and 6.4% as of December 31, 2005.

6. Inventories

Inventories, net, consist of the following:

	December 31, 2006	December 31, 2005
Finished goods	$2,371,346	$ 373,818
Reserve for obsolete and slow-moving inventory	(293,956)	(154,367)
Inventories, net	$2,077,390	$ 219,451

The Company periodically reviews its product inventories on hand. Inventory levels are evaluated by management relative to product demand, remaining shelf life, future marketing plans and other factors, and reserves for obsolete and slow-moving inventories are recorded for amounts which may not be realizable. The Company recorded provisions for excess inventory of $140,000 and $154,367 in the years ended December 31, 2006 and 2005, respectively.

7. Prepaids and Other Current Assets

Prepaid expenses and other current assets consists of the following:

	December 31, 2006	December 31, 2005
Prepaid insurance	$ 804,790	$771,707
New Drug Application filing fee — refundable	672,150	—
Other prepaid costs	205,745	25,546
Prepaid expenses and other current assets	$1,682,685	$797,253

At December 31, 2006 prepaid expenses and other current assets included the refundable portion of a filing fee paid to the FDA for a New Drug Application (NDA) the Company submitted for Amoxicillin PULSYS in 2006. The total NDA filing fee paid was $896,200. The remaining $224,050 balance of the NDA fee paid, which was charged to general and administrative expense in 2006, is potentially refundable to the Company should the Company meet the requirements for a small business waiver. The Company's application for the waiver is currently under review by the FDA and Small Business Administration.

8. Property and Equipment

Property and equipment consist of the following:

	Estimated Useful Life (Years)	December 31, 2006	December 31, 2005
Construction in progress	n/a	$ 554,673	$ 535,463
Computer equipment	3	1,024,149	1,010,757
Furniture and fixtures	3-10	1,405,918	1,405,918
Equipment	3-10	9,140,957	9,197,693
Leasehold improvements	Shorter of economic lives or lease term	8,738,230	8,719,668
Subtotal		20,863,927	20,869,499
Less — accumulated depreciation		(9,099,300)	(6,418,872)
Property and equipment, net		$11,764,627	$14,450,627

Depreciation expense for the years ended December 31, 2006, 2005 and 2004 was $2,699,111, $2,886,743 and $2,129,501, respectively.

9. Intangible Assets

Intangible assets at December 31, 2006 and December 31, 2005 consist of the following:

	December 31, 2006		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Keflex brand rights	$10,954,272	$(2,738,580)	$8,215,692
Keflex non-compete agreement	251,245	(125,610)	125,635
Patents acquired	120,000	(84,000)	36,000
Intangible assets	$11,325,517	$(2,948,190)	$8,377,327

	December 31, 2005		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Keflex brand rights	$10,954,272	$(1,643,148)	$9,311,124
Keflex non-compete agreement	251,245	(75,366)	175,879
Patents acquired	120,000	(72,000)	48,000
Intangible assets	$11,325,517	$(1,790,514)	$9,535,003

On June 30, 2004, the Company acquired the U.S. rights to the Keflex brand of cephalexin from Eli Lilly and Company. The purchase price was $11.2 million, including transaction costs, which was paid in cash from the Company's working capital. The identified intangible assets acquired consisted of the Keflex brand and a non-compete agreement with Lilly. The Company did not acquire customer lists or sales personnel from Lilly.

In the event the Company is able to develop and commercialize a PULSYS-based Keflex product, another cephalexin product relying on the acquired NDAs, or other pharmaceutical products using the acquired trademarks, Eli Lilly will be entitled to royalties on these new products. Royalties, at 10 percent of sales value, are payable on a new product by new product basis for five years following the first commercial sale for each new product, up to a maximum aggregate royalty per calendar year. In 2006 the Company launched its Keflex 750 mg product, which is covered by the agreement and is subject to the royalty. All royalty obligations with respect to any defined new product cease after the fifteenth anniversary of the first commercial sale of the first defined new product.

The fair market values of the individual Keflex intangible assets acquired were evaluated by an unrelated third party valuation consulting firm, and the Company has recorded the individual fair market values of these intangible assets accordingly. The allocation of the purchase price was:

Keflex brand rights	$10,954,272
Keflex non-compete agreement	251,245
Total	$11,205,517

Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives. The Keflex brand rights are amortized over 10 years, the non-compete agreement with Lilly is amortized over five years, and certain acquired patents are amortized over 10 years.

Amortization expense for acquired intangible assets with definite lives was $1,157,676, $1,157,676 and $584,838 for the years ending December 31, 2006, 2005 and 2004, respectively. For the next five years, annual amortization expense for acquired intangible assets is expected to be approximately $1,200,000 for 2007 and 2008, and approximately $1,100,000 for 2009, 2010 and 2011.

10. Borrowings

The Company's obligations on borrowings are as follows:

	December 31, 2006	December 31, 2005
Merrill Lynch Capital term loan	$6,888,889	$ —
Lines of credit — equipment lender	—	1,492,412
Montgomery County note payable	75,000	75,000
Total	$6,963,889	$1,567,412

Principal payments under borrowings are as follows:

Year Ending December 31,	
2007	$ 2,741,667
2008	2,666,667
2009	1,555,555
Total borrowings	6,963,889
Less: Current portion	(6,963,889)
Noncurrent portion	$ —

Merrill Lynch Term Loan

On June 30, 2006, the Company entered into a $12 million senior secured credit facility with Merrill Lynch Capital, consisting of an $8 million term loan ("Term Loan") and a $4 million revolving loan facility ("Revolving Loan").

The Term Loan matures on June 30, 2009 and is payable in 36 equal monthly payments of principal. Interest on the outstanding balance of the Term Loan is payable monthly at an annual rate equal to one-month LIBOR plus 5.0 percent, which at December 31, 2006 equaled 10.35 percent. The Company borrowed the entire Term Loan commitment of $8 million at closing on June 30, 2006, and received net proceeds of $7,792,976. From the net loan proceeds, $987,008 was used to fully repay existing bank loans. The Company incurred $207,024 in debt issuance costs, which are included as a component of Deposits and Other Assets and are being amortized using the effective interest method as additional interest expense over the expected 36 month loan term. If the Term Loan is prepaid, the Company is required to pay a prepayment fee of 2.0 percent, 1.25 percent, or 0.75 percent, if the prepayment is made within the first, second, or third years after closing (June 30, 2006), respectively.

The Revolving Loan commitment provides for up to $4 million in borrowing capacity with a commitment expiry date of March 30, 2010, with an interest rate equal to one-month LIBOR plus 3.75 percent per annum. Credit available under the Revolving Loan is subject to certain borrowing base conditions based on eligible accounts receivable of the Company. The Revolving Loan commitment may also be used for the issuance of letters of credit, up to an aggregate amount of $1,000,000. There were no borrowings or letters of credit outstanding under this facility at December 31, 2006. An unused line fee of 0.045 percent per month is payable on the average unused daily balance of the Revolving Loan commitment. If the Revolving Loan commitment is terminated prior to the expiration date of March 30, 2010, the Company is required to pay a deferred commitment fee of 2.0 percent, 1.25 percent, 0.75 percent, or 0.25 percent of the Revolving Loan commitment amount if the termination is made within the first, second, third or fourth years after closing (June 30, 2006), respectively.

Pursuant to the credit and security agreement, the Company granted a security interest in substantially all of its assets existing at the date of closing as well as those acquired during the term of the agreement, to Merrill Lynch Capital, excluding intellectual property, which is subject to a negative pledge under which the Company has agreed

not to grant a security interest in its intellectual property, as defined, without the consent of Merrill Lynch Capital. The agreement does not require the issuance of stock warrants or other equity types of securities.

The agreement restricts the Company's ability to incur additional debt, pay dividends, repurchase stock, or engage in specified other transactions outside the normal course of business, as long as borrowings are outstanding under the agreement. The credit and security agreement also requires the Company to be in compliance with certain financial covenants, including achievement of a minimum quarterly amount of revenue and maintenance of a minimum liquidity level (cash and marketable securities of $5,000,000). On December 8, 2006, the agreement was amended to remove the financial covenant for revenue / invoiced products for the quarters ending December 31, 2006 and March 31, 2007. Beginning with the quarter ending June 30, 2007 and continuing thereafter, the financial covenant for minimum quarterly revenue is $5,000,000, an amount which significantly exceeds quarterly revenue recorded by the Company in prior periods and which requires the successful commercialization and market acceptance of the Company's Keflex 750 mg product. The financial covenant to maintain a minimum liquidity level of $5,000,000 has not been removed from the credit and security agreement, and the Company's operating losses, in the absence of additional financial resources, create a risk that the covenant might not be met as soon as the three months ending March 31, 2007. In addition, the agreement contains a material adverse change clause under which the lender could accelerate the Company's obligations under the credit and security agreement upon either (1) the occurrence of an event that could reasonably be expected to result in a material adverse change, or (2) if the lender determines, in its good faith opinion, that there is a reasonable likelihood that the Company will fail to comply with one or more of the financial covenants during the succeeding financial reporting period. Due to the subjective acceleration clause, the entire outstanding balance of the term loan is classified as a current liability, pursuant to FASB Technical Bulletin 79-3, *"Subjective Acceleration Clauses in Long-Term Debt Agreements."*

If the Company borrows in the future under the Revolving Loan commitment, the balance would be classified as a current liability, because the loan agreement contains both a subjective acceleration clause and a requirement to maintain a lock-box arrangement whereby remittances from the Company's customers immediately reduce the outstanding obligation. In accordance with EITF 95-22, *"Balance Sheet Classification of Borrowings Outstanding under Revolving Credit Agreements that include both a Subjective Acceleration Clause and a Lock-box Arrangement,"* indebtedness under a revolving credit facility containing such provisions should be considered a short-term liability.

Lines of Credit

In February 2002, the Company entered into a $2.0 million line of credit facility to finance the purchase of specified equipment based on approved equipment schedules. The implicit interest rates were between 8.35% and 9.35%. The Company has granted a security interest in the assets purchased under the credit line. During 2006 and 2005 the Company had no draw downs under the line of credit. During 2006 and 2005, the Company repaid $115,389 and $138,435, respectively. The balances outstanding at December 31, 2006 and 2005 were zero and $115,389, respectively.

In March 2002, the Company entered into a $500,000 line of credit facility with a bank to finance the purchase of equipment. The interest rate was floating 30-Day LIBOR plus 250 basis points or fixed cost of funds plus 250 basis points. Each draw required monthly repayment of principal plus interest based upon a 48-month repayment schedule. The line of credit had a first lien on all assets purchased with the proceeds of this line. As of December 31, 2005, the Company had a $41,924 restricted account (see Note 2) with the bank to be used as collateral for this line of credit, which was released in 2006 upon repayment of the loan. During 2006 and 2005, the Company had no draw downs under the line of credit and repaid $41,924 and $123,076, respectively. The balances outstanding at December 31, 2006 and 2005 were zero and $41,924, respectively.

In July 2003, the Company entered into a $5.5 million line of credit facility with a bank to finance the purchase of equipment associated with the fit-out of the Company's corporate, research and development facility. The facility had an interest rate of floating 30-Day LIBOR plus 280 basis points or fixed cost of funds plus 280 basis points. Each

draw required monthly repayment of principal plus interest based upon a 36-month repayment schedule for computer equipment or a 48-month repayment schedule for all other equipment. The line of credit had a first lien on all assets purchased with the proceeds of the line. As collateral for the line of credit, the Company maintained a restricted account with the bank in the amount of $500,000, which was released in 2006 upon repayment of the loans in full (see Note 2). During 2006 and 2005, the Company had no draws and repaid $1,335,099 and $737,891, respectively. The balances outstanding under this facility at December 31, 2006 and 2005 were zero and $1,335,099, respectively.

Montgomery County Note Payable

In December 2001, the Company entered into an Economic Development Fund Agreement with Montgomery County, Maryland. The primary purpose of the Economic Development Fund is to assist private employers who are located, planning to locate or substantially expand operations in Montgomery County. In September 2002, the Company received a $75,000 loan from the County. According to the agreement, the County will permanently forgive part or all of the $75,000 loan principal balance together with the accrued interest if certain conditions relating to employment levels and capital investment are met. A final determination as to whether these conditions have been satisfied has not yet been made. However, because it is possible that repayment may be required within the next year, should the conditions for forgiveness not be met, the $75,000 balance has been classified as a current liability. The Company must also repay the entire $75,000 if it relocates to a site outside Montgomery County, or moves all or substantial parts of its business outside the county, within 5 years of the date of the promissory note.

11. Accrued Expenses and Advances

Accrued expenses and advances consist of the following:

	December 31,	
	2006	2005
Research and development expenses	$1,695,628	$1,546,469
Sales and marketing expense	1,598,437	—
Severance — current portion	1,094,375	1,870,479
Bonus	1,081,503	849,078
Product returns	937,044	791,282
Professional fees	734,250	352,445
Insurance and benefits	228,009	179,109
Liability for exercised unvested stock options	18,632	42,770
Advance payment for potential sale of Keflex assets	—	1,000,000
Other expenses	429,346	440,099
Total accrued expenses	$7,817,224	$7,071,731

Accrued Severance

In July and September 2005, the Company reduced its workforce a total of approximately 38% as part of a cost-saving initiative. It recorded a charge of $3,973,265 for severance costs related to salaries and benefits, a non-cash benefit of $512,488 for the reversal of cumulative amortization of deferred stock-based compensation related to forfeited stock options, and a charge of $140,366 for the remaining cost of the New Jersey office lease. In November 2004, the Company implemented steps to reduce its expenses, as a result of the unexpected termination of the GSK collaboration as well as the discontinuance of the generic clarithromycin program. The Company reduced its workforce approximately 18% and recorded a charge of $497,049 for severance costs related to salaries and benefits, a non-cash credit of $159,962 for the reversal of cumulative amortization of deferred stock-based

compensation related to cancelled stock options, and a non-cash charge of $49,397 for stock-based compensation related to modification of stock option agreements.

Severance and related costs incurred in connection with the workforce reductions in 2005 and 2004 were recorded as follows:

	December 31, 2005		
	Research & Development Expense	Selling, General & Administrative Expense	Total
Severance — salaries and benefits	$2,847,220	$1,126,045	$3,973,265
Stock-based compensation — forfeitures	(182,581)	(329,907)	(512,488)
Accrued rent for closed office location	105,275	35,091	140,366
Total	$2,769,914	$ 831,229	$3,601,143

	December 31, 2004		
	Research & Development Expense	Selling, General & Administrative Expense	Total
Severance — salaries and benefits	$377,757	$119,292	$ 497,049
Stock-based compensation — forfeitures	(60,786)	(99,176)	(159,962)
Stock-based compensation — modification of options	49,397	—	49,397
Total	$366,368	$ 20,116	$ 386,484

The following table summarizes the activity in 2006 and 2005 for the liability for the cash portion of severance costs related to the reductions-in-force:

	December 31, 2006			
Accrued Severance — 2006 Activity	Beginning Balance	Reversal	Cash Paid	Ending Balance
2005 Workforce reduction	$3,105,873	$(358,530)	$(1,652,966)	$1,094,377
Current portion	$1,870,479			$1,094,375
Noncurrent portion	1,235,394			—
	$3,105,873			$1,094,375

	December 31, 2005			
Accrued Severance — 2005 Activity	Beginning Balance	Charge	Cash Paid	Ending Balance
2005 Workforce reduction	$ —	$3,973,265	$ (867,392)	$3,105,873
2004 Workforce reduction	286,515	—	(286,515)	—
	$286,515	$3,973,265	$(1,153,907)	$3,105,873

In 2006, an executive was rehired for whom a severance charge had previously been recorded upon his termination in 2005. Upon his rehiring, the remaining accrued severance applicable to that individual of $358,530 that was no longer payable was reversed, and the benefit was recorded as a reduction in Selling, General and Administrative Expense.

The remaining balance of $1,094,375 at December 31, 2006 will be paid through September 2007.

Advance Payment for Potential Sale of Keflex Assets

In August 2005, Advancis entered into an agreement in principle with a private company for the potential sale of its Keflex assets, including the rights to the U.S. brand and inventories. As part of the agreement, the potential buyer made a $1,000,000 payment to Advancis, which provided it with exclusive negotiating rights through December 31, 2005. The payment was recorded as an advance, since, under certain conditions, the payment could become refundable or, if the sale were to have been completed, the $1,000,000 payment would have been applied to the purchase price. The two parties did not enter into a definitive agreement for the asset sale, and in January 2006, Advancis decided to retain the Keflex assets. The agreement in principle expired on February 28, 2006. Accordingly, the advance payment of $1,000,000 was recognized as other income in 2006.

12. Preferred Stock — Undesignated

On October 22, 2003, the Company's certificate of incorporation was amended to authorize the issue of up to 25,000,000 shares of undesignated preferred stock. The Company's Board of Directors, without any further action by the Company's stockholders, is authorized to issue shares of undesignated preferred stock in one of more classes or series. The Board may fix the rights, preferences and privileges of the preferred stock. The preferred stock could have voting or conversion rights that could adversely affect the voting power or other rights of common stockholders. As of December 31, 2006 and 2005, no shares of preferred stock have been issued.

13. Common Stock

Effective with the Company's initial public offering on October 22, 2003, the Company's certificate of incorporation was amended to increase the number of authorized shares of common stock to 225,000,000.

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding.

Shares Reserved for Future Issuance

The Company has 2,396,357 common shares reserved for future issuance in connection with warrants issued in the April 2005 private placement (see Note 14).

14. Private Placements of Common Stock

In December 2006, the Company completed a private placement of 6,000,000 shares of its common stock at a price of $3.00 per share, resulting in gross proceeds to the Company of $18.0 million. Net proceeds to the Company after deducting commissions and expenses were approximately $16.7 million. No warrants were issued in the transaction. Pursuant to the terms of the registration rights agreement, the Company filed with the SEC a registration statement on Form S-3 covering the resale of common stock. The registration rights agreement provides that if a registration statement is not effective within 90 days of closing, or if the Company does not subsequently maintain the effectiveness of the registration statement, then in addition to any other rights the investor may have, the Company will be required to pay the investor liquidated damages, in cash, equal to one percent per month of the aggregate purchase price paid by such investor. The SEC declared the Company's Form S-3 effective on December 29, 2006, which was within 90 days of closing.

In April 2005, the Company completed a private placement of 6,846,735 shares of its common stock at a price of $3.98 per share and warrants to purchase a total of 2,396,357 shares of common stock at an exercise price of $4.78 per share, resulting in gross proceeds to the Company of $27.25 million. Net proceeds to the Company after deducting commissions and expenses were approximately $25.8 million. The warrants are exercisable for five years. Pursuant to the terms of the registration rights agreement, the Company filed with the SEC a registration statement on Form S-3 covering the resale of common stock. The registration rights agreement provides that if a

registration statement is not effective within 60 days of closing, or if the Company does not subsequently maintain the effectiveness of the registration statement, then in addition to any other rights the investor may have, the Company will be required to pay the investor liquidated damages, in cash, equal to one percent per month of the aggregate purchase price paid by such investor. The SEC declared the Company's Form S-3 effective on June 1, 2005, which was within 60 days of closing.

The Company views the registration rights agreement containing the liquidated damages provision as a separate freestanding contract which has nominal value, and the Company has followed that accounting approach, consistent with FASB Staff Position No. EITF 00-19-2, *"Accounting for Registration Payment Arrangements."* Under this approach, the registration rights agreement is accounted for separately from the financial instrument. Accordingly, the classification of the warrants has been determined under EITF 00-19, *"Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock,"* and the warrants have been accounted for as permanent equity. Under FSP No. EITF 00-19-02, registration payment arrangements are measured in accordance with SFAS No. 5, *"Accounting for Contingencies."* Should the Company conclude that it is probable that a liability for liquidated damages will occur, the Company will record the estimated cash value of the liquidated damages liability at that time.

FSP No. EITF 00-19-02 requires disclosure of the maximum potential amount of consideration, undiscounted, that an issuer could be required to transfer under the registration payment arrangement. For the private placements that closed in December 2006 and April 2005, the Company's maximum potential liquidated damages are approximately $4.3 million and $3.6 million, respectively, as of December 31, 2006. The maximum levels of liquidated damages would only occur should the Company's registration statements be ineffective for the entire required periods under the registration rights agreements.

15. Stock Option Plan

The Company currently grants stock options under the Stock Incentive Plan (the "Plan"). The number of shares available for issuance under the Plan is 7,848,182.

Options granted under the Plan may be incentive stock options or non-statutory stock options. Stock purchase rights may also be granted under the Plan. Incentive stock options may only be granted to employees. The compensation committee of the Board of Directors determines the period over which options become exercisable. Options granted to employees and consultants normally vest over a 4-year period. Options granted to directors, upon their initial appointment or election, vest monthly over periods of 36 or 48 months. Annual director and advisor grants vest monthly over 12 months. Director and advisor grants are exercisable on the date of grant but are restricted, subject to repurchase until vested. The exercise price of incentive stock options and non-statutory stock options shall be no less than 100% of the fair market value per share of the Company's common stock on the grant date. The term of all options outstanding is 10 years. As of December 31, 2006 and 2005, there were 1,756,481 and 2,598,019 shares of common stock available for future option grants, respectively.

The following table summarizes the activity of the Company's stock option plan for the years ended December 31, 2006, 2005 and 2004:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Yrs)	Aggregate Intrinsic Value
Outstanding, December 31, 2003	2,235,488	$3.45		
Granted	1,660,550	8.00		
Exercised	(26,764)	0.61		
Cancelled	(132,548)	5.15		
Outstanding, December 31, 2004	3,736,726	5.43		
Granted	1,926,350	3.24		
Exercised	(171,155)	0.59		
Cancelled	(1,396,504)	4.89		
Outstanding, December 31, 2005	4,095,417	4.79		
Granted	1,322,870	2.24		
Exercised	(558,377)	0.63		
Cancelled	(481,332)	6.86		
Outstanding, December 31, 2006	4,378,578	$4.30	7.9	$5,406,124
Exercisable, December 31, 2006	2,574,111	$4.86	7.6	$3,111,107

The total intrinsic value of options exercised during the year ended December 31, 2006 was $787,345. Cash received by the Company upon the issuance of shares from option exercises was $352,737. The Company's policy is to issue new shares of common stock to satisfy stock option exercises.

A summary of the Company's nonvested options as of and for the year ended December 31, 2006 is presented below:

	Number of Nonvested Stock Options	Weighted Average Grant Date Fair Value
Outstanding, December 31, 2005	2,009,729	$4.21
Granted	1,322,870	1.57
Vested	(1,333,053)	2.73
Forfeited	(80,106)	2.59
Outstanding, December 31, 2006	1,919,440	$3.48

The following table summarizes information about stock options outstanding, and exercisable at December 31, 2006:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
December 31, 2006					
$0.35 to $0.93	673,338	7.3	$0.77	605,966	$0.78
$1.28 to $1.79	1,219,212	8.6	1.51	432,070	1.47
$2.75 to $3.59	398,152	9.2	2.98	143,904	2.79
$4.05 to $5.57	819,690	8.4	4.37	397,044	4.37
$8.40 to $10.00	1,268,186	7.0	9.23	995,127	9.30
	4,378,578	7.9	$4.30	2,574,111	$4.86

16. Stock-Based Compensation

The Company has recorded stock-based compensation expense for the grant of stock options to employees and to nonemployees as follows:

	December 31,		
Stock-Based Compensation Expense:	2006	2005	2004
Employees:			
SFAS 123R fair-value method	$3,080,790	$ —	$ —
APB 25 intrinsic value method	—	658,935	3,626,887
Subtotal — Employees	3,080,790	658,935	3,626,887
Nonemployees:			
Fair value method	323,273	(123,149)	26,370
Total	$3,404,063	$ 535,786	$3,653,257

	December 31,		
Included in Income Statement Captions as follows:	2006	2005	2004
Research and development expense	$1,434,664	$159,699	$1,172,973
Selling, general and administrative expense	1,969,399	376,087	2,480,284
Total	$3,404,063	$535,786	$3,653,257

Employees. Prior to January 1, 2006, the Company's share-based awards were accounted for by the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *"Accounting for Stock Issued to Employees,"* (APB 25) and related interpretations. Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123R, *"Share-Based Payment"* (SFAS 123R). This Statement replaces SFAS No. 123 and supersedes APB 25. SFAS 123R requires that employee share-based compensation be measured using a fair value method and that the resulting compensation cost be recognized in the financial statements. The Company adopted SFAS 123R using the modified prospective transition method, which requires the recognition of compensation expense under the Statement on a prospective basis only. Accordingly, prior period financial statements have not been restated. Under this transition method, stock-based compensation cost for 2006 includes (a) compensation cost for all share-based awards granted prior to, but not yet vested as of, January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation

cost for all share-based awards granted subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the fair value provisions of SFAS 123R.

Under APB 25, the Company had recorded deferred stock-based compensation for certain stock options granted in prior years with an exercise price below the estimated fair market value at the date of grant. The deferred stock-based compensation was amortized as a charge to expense over the related vesting periods of the options. In accordance with SFAS 123R, effective January 1, 2006, the Company reversed the remaining balance of deferred stock-based compensation of $623,051 against Capital in Excess of Par Value.

SFAS 123R also requires the Company to estimate forfeitures in calculating the expense related to share-based compensation rather than recognizing forfeitures as a reduction in expense as they occur. Prior to the adoption of SFAS 123R, the Company accounted for forfeitures as they occurred as permitted under previous accounting standards. The cumulative effect adjustment of adopting the change in estimating forfeitures was not considered material to the financial statements upon implementation as of January 1, 2006 or for the year ended December 31, 2006.

The Company records compensation expense over the requisite service period, which is equal to the vesting period. For awards granted prior to January 1, 2006, compensation expense is recognized on a graded-vesting basis over the vesting term. For awards granted on or after January 1, 2006, compensation is recognized on a straight-line basis over the vesting term. All share-based compensation costs are charged to expense and not capitalized.

As of December 31, 2006, the total unrecognized compensation cost related to nonvested stock awards was $2,666,610, and the related weighted-average period over which it is expected to be recognized is approximately 2.2 years.

As a result of the adoption of SFAS 123R, the Company's net loss for 2006 was approximately $2,552,000 higher than it would have been under the Company's previous intrinsic value method of accounting for share-based compensation. Basic and diluted net loss per common share for the twelve months ended December 31, 2006 were negatively impacted by the change in accounting method by approximately $0.08 per share. The adoption of SFAS 123R had no effect on the Company's operating cash flows or financing cash flows, as the Company has not realized the benefits of tax deductions in excess of recognized compensation costs due to its net operating loss position.

The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provision of SFAS 123 to options granted under the Company's stock-based compensation plan for the years ended December 31, 2005 and 2004. For purposes of this pro forma disclosure, the value of the options is estimated using the Black-Scholes option-pricing model and amortized to expense using a graded vesting schedule with forfeitures recognized as a reduction in expense as they occur.

	Year Ended December 31,	
	2005	2004
Net loss, as reported	$(32,988,577)	$(34,004,713)
Add — Stock-based employee compensation expense determined under the intrinsic value method	658,935	3,626,887
Less — Stock-based employee compensation expense determined under the fair value based method	(3,298,472)	(8,491,814)
Pro forma net loss applicable to common stockholders	$(35,628,114)	$(38,869,640)
Net loss per share:		
Basic and diluted, as reported	$ (1.20)	$ (1.50)
Basic and diluted, pro forma	$ (1.30)	$ (1.71)

The weighted average fair value of options granted to employees during 2006, 2005 and 2004 was $1.51, $2.13 and $5.33 per share, respectively. The fair value of each option grant was estimated on the date of grant using the Black-Scholes options pricing model with the following assumptions for grants in 2006, 2005 and 2004:

	December 31,		
	2006	2005	2004
Expected term (in years)	6.25	5	5
Risk-free interest rate	4.57%	3.81%	4.09%
Volatility	75.0%	79.6%	80.0%
Dividend yield	0%	0%	0%

The Company has elected to determine the expected term of share-based awards granted subsequent to January 1, 2006 using the transition approach provided by Staff Accounting Bulletin No. 107, under which an expected term of 6.25 years may be used for four-year grants with a ten-year contractual term. Due to the limited Company-specific historical and implied volatility data, the Company has based its estimate of expected future volatility upon a combination of its historical volatility together with the average of volatility rates of comparable public companies. The risk-free rate is based on U.S. Treasury yields in effect at the time of grant corresponding with the expected term of the options. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by the employees who receive equity awards.

Nonemployees. The Company has recorded stock-based compensation expense for options granted to nonemployees, including consultants, Scientific Advisory Board (SAB) members and contracted sales representatives based on the fair value of the equity instruments issued. Stock-based compensation for options granted to non employees is periodically remeasured as the underlying options vest in accordance with Emerging Issues Task Force Issue No. 96-18, *"Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services."* The Company recognizes an expense for such options throughout the performance period as the services are provided by the nonemployees, based on the fair value of the options at each reporting period. The options are valued using the Black-Scholes option pricing model. For graded-vesting options, a final measurement date occurs as each tranche vests. As of December 31, 2006, the balance of unamortized stock-based compensation for options granted to non-employees was approximately $306,000. This amount will be adjusted based on changes in the fair value of the options at the end of each reporting period. As of December 31, 2006, 118,011 options are outstanding and exercisable for non employees.

Restricted Stock

Certain of the Company's directors, consultants and employees (and/or immediate family members or related entities to which certain of those individuals have transferred their options or shares of common stock) have entered into the Company's standard form of stock restriction agreement as a condition to their exercise of options to acquire common stock pursuant to the Plan. These agreements provide, among other things, for a right of first refusal to the Company in connection with the option holder's sale of the common stock, as well as the right for the Company to purchase the stockholder's common stock in the event that the stockholder's relationship with the Company is terminated under certain circumstances. Shares issued under non-statutory stock options exercised prior to vesting are subject to forfeiture in accordance with the vesting schedule of the granted stock options. Prior to 2004, certain of the Company's employees, board members and consultants exercised unvested stock options, awarded under the Company's Stock Incentive Plan, to acquire a total of 162,281 shares of restricted common stock. There were no such exercises in 2004, 2005 or 2006. At December 31, 2006 and 2005, 30,052 and 71,032 shares, respectively, of restricted common stock remain unvested pursuant to awards.

For all exercises of stock options into unvested restricted stock after March 2002, the Company recorded a liability for the amount of the proceeds received, which is reclassified to equity upon the vesting of the restricted

stock. As of December 31, 2006 and 2005, $18,632 and $42,770 related to 30,052 and 68,983 shares of restricted stock, respectively, were recorded as a liability.

Of the stock options exercised in 2001 into unvested restricted stock, Dr. Rudnic and two affiliated trusts exercised a total of 295,069 non-statutory stock options in October 2001. The exercise price was paid through the issuance of full-recourse promissory notes in the aggregate principal amount of $121,500. Interest accrued on the notes at 5.50% and the term of the notes was five years. The shares issued upon exercise of the options were pledged as security for the repayment of the promissory notes (the "Pledge"). In addition, pursuant to the terms of a stock restriction agreement, all of these shares were subject to repurchase by the Company upon any termination of Dr. Rudnic's employment (the "Termination Repurchase Right"). In February 2002, the stock restriction agreement was amended to provide the Company with an additional right, upon the Company's request, to repurchase 54,642 of the shares from Dr. Rudnic if the Company failed to meet certain performance milestones during 2002 (the "Milestone Repurchase Right"). In January 2003, the Company's Board of Directors decided not to exercise the Company's Milestone Repurchase Right. The Milestone Repurchase Right was never exercised by the Company and lapsed in February 2003. The 54,642 shares remain subject to the Pledge and the Termination Repurchase Right. In October 2006, the promissory notes were fully repaid.

17. Income Taxes

The Company has not recorded any tax provision or benefit for the years ended December 31, 2006, 2005 and 2004. The Company has provided a valuation allowance for the full amount of its net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carryforwards cannot be sufficiently assured at December 31, 2006 and 2005.

Deferred tax assets consist of the following:

	December 31,	
	2006	2005
Net operating loss carryforwards	$ 47,842,353	$ 31,161,022
Start-up costs	999,992	1,666,653
Deferred revenue	4,704,335	4,629,075
Depreciation and amortization	80,837	19,269
Stock-based compensation	653,822	2,742,775
Advance payment for potential sale of Keflex brand rights	—	398,200
Accrued severance	300,835	1,236,789
Accrued research and development, accrued returns and other items	1,331,236	847,868
Patent costs	531,175	387,520
Research and experimentation tax credit	6,126,272	4,941,432
Deferred tax assets	62,570,857	48,030,603
Valuation allowance	(62,570,857)	(48,030,603)
Net deferred tax assets	$ —	$ —

The effective tax rate differs from the U.S. federal statutory tax rate of 34% due to the following:

	Year Ended December 31,		
	2006	2005	2004
U.S. federal statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of federal tax benefit	(5.8)%	(5.8)%	(4.6)%
Permanent items, primarily stock-based compensation	2.9%	0.2%	0.4%
Research and experimentation tax credit	(2.8)%	(6.3)%	(4.2)%
Change in valuation allowance	39.7%	45.9%	42.4%
Effective tax rate	(0.0)%	(0.0)%	(0.0)%

At December 31, 2006 and 2005, the Company had federal and state net operating loss carryforwards of approximately $120.6 million and $78.3 million, respectively, available to reduce future taxable income, which will begin to expire in 2020. At December 31, 2006, the Company had federal research and experimentation tax credit carryforwards of approximately $5.8 million which begin to expire in 2020 and state tax credit carryforwards of $0.4 million which begin to expire in 2018.

Under the provisions of Section 382 of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss and research and experimentation tax credit carryforwards which can be utilized in future years. During 2005 and prior years, the Company may have experienced such ownership changes. Ownership changes in 2001 and 2005 may have created annual limitations of approximately $900,000 and $3,800,000, respectively. There were no ownership changes under Section 382 in other years.

18. 401(k) Savings Plan and Employee Stock Purchase Plan

During 2000, the Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company's Board of Directors has discretion to match contributions made by the Company's employees. To date, no matching contributions have been made by the Company.

During 2003, the Company adopted an employee stock purchase plan which provides for the issuance of up to 100,000 shares of common stock. This plan, which is intended to qualify under Section 423 of the Internal Revenue Code, provides the Company's employees with an opportunity to purchase shares of its common stock through payroll deductions. Options to purchase the common stock may be granted to each eligible employee periodically. The purchase price of each share of common stock will not be less than the lesser of 85% of the fair market value of the common stock at the beginning or end of the option period. Participation is limited so that the right to purchase stock under the purchase plan does not accrue at a rate which exceeds $25,000 of the fair market value of the Company's common stock in any calendar year. To date, the plan has not been activated, and no shares have been issued under this plan.

19. Commitments and Contingencies

Leases

In August 2002, the Company entered into a 10-year lease for its corporate, research and development facility in Germantown, Maryland, which is renewable for two periods of five consecutive years each at the end of the original term. The Company took possession of the lease space during 2003. In conjunction with the execution of the lease agreement, the Company provided the landlord with a letter of credit, which the Company collateralized with a restricted cash deposit in the amount of $566,180 and $753,000 at December 31, 2006 and 2005 (see Note 2).

The lease includes scheduled base rent increases over the term of the lease. The total amount of the base rent payments will be charged to expense on the straight-line method over the term of the lease (excluding renewal periods). In 2004 and 2003, the Company received $87,078 and $830,010, respectively, in cash from the landlord in connection with the build-out of the facility. These amounts were recorded as deferred rent and are being amortized on a straight-line basis as a reduction to rent expense over the term of the lease.

In August 2004, the Company leased additional space adjacent to its Germantown, Maryland, facility. This lease, which includes a rent holiday and scheduled rent increases annually over its term, is being charged to expense on a straight-line basis over the entire term of the lease, which expires May 31, 2013. In conjunction with the execution of the lease agreement, the Company provided the landlord with a letter of credit, which the Company collateralized with a restricted cash deposit in the amount of $306,000 at December 31, 2006 and 2005. (see Note 2).

The Company also leased additional laboratory space in Gaithersburg, Maryland, under a lease which expired in November 2005, and office space in New Jersey under a lease which expired in September 2006. The Company also leases office equipment expiring at various dates through 2009.

Rent expense under all leases, including deferred rent adjustments as well as the accrual of the remaining rent of $140,366 for the New Jersey office closed in 2005, was $2,019,610, $2,472,819, and $1,599,662 for the years ended December 31, 2006, 2005 and 2004, respectively.

Future minimum lease payments under noncancelable operating leases at December 31, 2006 are as follows:

Year Ending December 31,	Operating Leases
2007	$ 2,079,474
2008	2,139,250
2009	2,156,210
2010	2,214,399
2011	2,155,021
Thereafter	3,163,339
Total	$13,907,693

Royalties

In the event the Company is able to develop and commercialize a PULSYS-based Keflex product, another cephalexin product relying on the acquired NDAs, or other pharmaceutical products using the acquired trademarks, Eli Lilly will be entitled to royalties on these new products. In 2006 the Company launched its Keflex 750 mg product, which is covered by the agreement and is subject to a royalty on net sales, as defined, of 10 percent. Royalties are payable on a new product by new product basis for five years following the first commercial sale for each new product, up to a maximum aggregate royalty per calendar year. All royalty obligations with respect to any defined new product cease after the fifteenth anniversary of the first commercial sale of the first defined new product.

Legal Proceedings

The Company is a party to legal proceedings and claims that arise during the ordinary course of business.

In December 2003, Aventis and Aventis Pharmaceuticals Inc., now part of sanofi-aventis, brought an action against Advancis, alleging, in essence, that the Advancis corporate name is infringing the plaintiff's trademark and seeking injunctive relief. A trial was held in May 2005, and the Court's decision, dated September 26, 2006, ruled in favor of sanofi-aventis and required the parties to jointly submit a proposed Permanent Injunction and Order, which was submitted on October 27, 2006. On October 31, 2006 the proposed Order was approved, which will cause

Advancis to surrender its trademark registrations for the "Advancis" name, and cease using the name in connection with its business, effective June 30, 2007.

No monetary damages were associated with the decision, and the Company does not believe there will be a significant financial impact in complying with the Court's decision.

20. Related Party Transactions

Loans to Executive Officer

In October 2001, the Company provided loans to Dr. Edward Rudnic, the Company's president, chief executive officer and a director, and two trusts affiliated with Dr. Rudnic, that were evidenced by full recourse notes in the aggregate principal amount of $121,500. The notes accrued interest at a fixed annual interest rate of 5.5%, with the interest payable annually, and were fully repaid together with accrued interest upon maturity in October 2006. At December 31, 2005, the total amount outstanding under the loans was $123,171, including accrued interest.

Consulting Arrangements

In December 2002, the Company entered into a consulting arrangement with Mr. James D. Isbister, then the chairman of the Company's board of directors, which provides for a payment to Mr. Isbister of $60,000 per year in exchange for consulting services. These consulting services include tactical advice and planning with regard to corporate operations, financing approaches, and product development and commercialization strategies.

Effective May 1, 2004, Mr. James D. Isbister retired as the chairman of the board of directors. At that time, the Company entered into a new agreement with Mr. Isbister which provides for a payment to him of up to $100,000 per year in exchange for consulting services. The initial term of the agreement is for 40 months, and it may be renewed by mutual agreement.

Also on May 1, 2004, Mr. Isbister and the Company entered into an agreement to amend the stock option agreements with Mr. Isbister, to provide for the continued vesting of unvested restricted stock and for accelerated vesting in the event of a termination by the Company of the consulting agreement with Mr. Isbister or a defined change in control of the Company. As a result of his change in status from director to consultant and the Company waiving its right to repurchase the restricted stock issued for options which had been early exercised by Mr. Isbister, the Company recorded a stock-based compensation charge of $489,951.

In December 2002, the Company entered into a consulting agreement with Jenefir D. Isbister, Ph.D., the spouse of Mr. James Isbister and a professor and research microbiologist at George Mason University. Under the terms of the consulting agreement, the Company pays Dr. Isbister $1,500 per day for consultation and research support services in connection with the Company's identification and development of pulsatile antibiotic delivery strategies. Due to the retirement of her husband from the Board of Directors on May 1, 2004, Dr. Isbister is no longer a related party. In 2004 (through May 2004), the Company paid an aggregate of $28,000 to Dr. Isbister under this agreement.

21. Quarterly Financial Data (Unaudited)

The following table presents unaudited quarterly financial data of the Company. The Company's quarterly results of operations for these periods are not necessarily indicative of future results of operations.

	Revenue	Operating Loss	Net Loss	Net Loss Applicable to Common Stockholders	Net Loss Per Share Applicable to Common Stockholders
Year ended					
December 31, 2006					
First quarter	$ 860,231	$ (8,866,141)	$ (7,597,350)	$ (7,597,350)	$(0.25)
Second quarter	336,357	(10,909,876)	(10,725,547)	(10,725,547)	(0.35)
Third quarter	2,369,975	(9,876,760)	(9,897,162)	(9,897,162)	(0.33)
Fourth quarter	1,243,847	(13,699,226)	(13,770,095)	(13,770,095)	(0.44)
Year ended					
December 31, 2005					
First quarter	$4,626,656	$(11,518,582)	$(11,388,603)	$(11,388,603)	$(0.50)
Second quarter	3,200,839	(9,555,757)	(9,312,832)	(9,312,832)	(0.34)
Third quarter	7,401,313	(6,169,988)	(5,880,240)	(5,880,240)	(0.20)
Fourth quarter	1,618,882	(6,714,736)	(6,406,902)	(6,406,902)	(0.22)

SCHEDULE II

ADVANCIS PHARMACEUTICAL CORPORATION

VALUATION AND QUALIFYING ACCOUNTS
Years Ended December 31, 2006, 2005, and 2004

	Balance at Beginning of Period	Additions	Deductions (1)	Balance at End of Period
Accounts receivable allowances:				
Year Ended December 31, 2006	$ 352,920	$ 821,165	$(957,155)	$ 216,930
Year Ended December 31, 2005	$ 128,569	$ 690,463	$(466,112)	$ 352,920
Year Ended December 31, 2004	$ —	$ 200,553	$ (71,984)	$ 128,569
Inventory reserves:				
Year Ended December 31, 2006	$ 154,367	$ 140,000	$ (411)	$ 293,956
Year Ended December 31, 2005	$ —	$ 154,367	$ —	$ 154,367
Year Ended December 31, 2004	$ —	$ —	$ —	$ —
Deferred tax asset valuation reserves:				
Year Ended December 31, 2006	$48,030,603	$14,540,254	$ —	$62,570,857
Year Ended December 31, 2005	$31,870,513	$16,160,090	$ —	$48,030,603
Year Ended December 31, 2004	$17,448,221	$14,422,292	$ —	$31,870,513

(1) Deductions represent utilization of the allowances. For accounts receivable, these include the deduction by customers of prompt pay discounts from their payments, chargebacks made by wholesalers to the Company, and writeoffs of bad debts, if any.

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Corporate Information

Executive Officers

Edward M. Rudnic, Ph.D.
President & Chief Executive Officer

Robert C. Low
Vice President, Finance & Chief Financial Officer

Robert W. Bannon
Vice President, Investor Relations & Corporate Communications

James Bruno
Vice President, Pharmaceutical Sales

Darren W. Buchwald
Vice President, Commercial Development, Sales & Marketing

Beth A. Burnside, Ph.D.
Vice President, Pharmaceutical Research

Susan P. Clausen, Ph.D.
Vice President, Clinical Research & Regulatory Affairs

Donald J. Treacy, Ph.D.
Vice President, Analysis & Pharmaceutical Quality

Sandra E. Wassink
Vice President, Pharmaceutical Development Operations

Board of Directors

R. Gordon Douglas, M.D.
Chairman

James H. Cavanaugh, Ph.D.
Director

Richard Dugan
Director

Wayne T. Hockmeyer, Ph.D.
Director

Edward M. Rudnic, Ph.D.
Director

Martin A. Vogelbaum
Director

Harold R. Werner
Director

Mrs. William McCormick Blair, Jr.
Senior Advisor

Corporate Headquarters
20425 Seneca Meadows Parkway
Germantown, MD 20876
301 944-6600 • www.advancispharm.com

Transfer Agent
Questions concerning lost stock certificates, address changes, stock transfers or other stockholder matters should be directed to:
American Stock Transfer & Trust Company
59 Maiden Lane, New York, NY 10038
800 937-5449 • www.amstock.com

Form 10-K
Copies of the Company's Form 10-K filed with the Securities and Exchange Commission along with other corporate information are available upon request by contacting the Company at:
20425 Seneca Meadows Parkway, Germantown, MD 20876
Attention: Investor Relations
301 944-6600

Annual Meeting
Advancis Pharmaceutical's annual meeting of stockholders will take place on May 21, 2007, at 3:00 p.m., local time, at the Company's corporate headquarters in Germantown, Maryland.

Independent Auditors
PricewaterhouseCoopers LLP
250 West Pratt Street, Suite 2100, Baltimore, MD 21201
410 783-7600

Legal Counsel
Dewey Ballantine LLP
1301 Avenue of the Americas, New York, NY 10019
212 259-8000

Trademarks

Common Stock Data
The Company's common stock has traded on The NASDAQ National Market under the symbol AVNC since the Company's initial public offering on October 17, 2003. As of March 31, 2007, the Company had 120 shareholders of record, approximately 2,890 beneficial shareholders and 36,401,854 shares of common stock outstanding.

For additional information, including an online version of Advancis Pharmaceutical's annual report, please visit our website at:
www.advancispharm.com

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