



# FORM 10-K

**Abraxis BioScience, Inc. – ABBI**

**Filed: March 16, 2005 (period: December 31, 2004)**

Annual report which provides a comprehensive overview of the company for the past year

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## PART I

**Item 1.** Business

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**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, 2004

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 0-33407

**American Pharmaceutical Partners, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State of Incorporation)

**1501 East Woodfield Road, Suite 300 East Schaumburg, IL 60173-5837**

(Address of principal executive offices,  
including zip code)

**68-0389419**

(I.R.S. Employer Identification No.)

**(847) 969-2700**

(Registrant's telephone number,  
including area code)

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 \$0.001 per share**

(Title of class)

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.

As of June 30, 2004, the aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately \$620.7 million based on the Nasdaq closing price of \$30.38 per common share on that date.

Indicate by check mark whether the registrant is an accelerated filer (as determined by Exchange Act 12b-2). Yes  No

As of March 8, 2005, the Registrant had 71,132,305 shares of Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Parts of the Registrant's Proxy Statement for its 2005 Annual Meeting of Stockholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of this report on Form 10-K.

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AMERICAN PHARMACEUTICAL PARTNERS, INC.

FORM 10-K

For the Year Ended December 31, 2004

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**PART I**

**Item 1. Business**

**Note Regarding Forward-Looking Statements**

Statements contained in this Annual Report on Form 10-K, which are not historical facts, are forward-looking statements, as the term is defined in the Private Securities Litigation Reform Act of 1995. Such forward-looking statements, whether expressed or implied, are subject to risks and uncertainties which can cause actual results to differ materially from those currently anticipated, due to a number of factors, which include, but are not limited to:

- the market adoption of our existing and new pharmaceutical products, including ABRAXANE™;
- the amount and timing of costs associated with the continuing launch of ABRAXANE™;
- the actual results achieved in further clinical trials of ABRAXANE™ may or may not be consistent with results achieved to date;
- the impact of competitive products and pricing;
- the ability to successfully manufacture products in an efficient, time-sensitive and cost effective manner;
- the impact on our products and revenues of patents and other proprietary rights licensed or owned by us, our competitors and other third parties;
- our ability, and that of our suppliers, to comply with laws, regulations, and standards, and the application and interpretation of those laws, regulations, and standards, that govern or affect the pharmaceutical industry, the non-compliance with which may delay or prevent the sale of our products;
- the difficulty in predicting the timing or outcome of product development efforts and regulatory approvals;
- the ability to successfully integrate the recent and potential future acquisitions;
- the availability and price of acceptable raw materials and component from third-party suppliers;
- evolution of the fee-for-service arrangements being adopted by our major wholesale customers;
- inventory reductions or fluctuations in buying patterns by wholesalers or distributors;
- the impact of recent legislative changes to the governmental reimbursement system.

Forward-looking statements also include the assumptions underlying or relating to any of the foregoing or other such statements. When used in this report, the words “may,” “will,” “should,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “continue,” and similar expressions are generally intended to identify forward-looking statements.

Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management’s opinions only as of the date hereof. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements. Readers should carefully review the factors described in *Business: Factors that May Affect Future Results of Operations* and other documents we file from time to time with the Securities and Exchange Commission, including the Quarterly Reports on Form 10-Q to be filed by us in fiscal year 2005.

**Overview**

We are a pharmaceutical company that develops, manufactures and markets injectable pharmaceutical products. We believe that we are the only independent U.S. public company with a primary focus on the injectable oncology, anti-infective and critical care markets, and we further believe that we offer one of the most comprehensive injectable product portfolios in the pharmaceutical industry. We manufacture products in each of the three basic forms in which injectable products are sold: liquid, powder and lyophilized, or freeze-dried.

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Our products are generally used in hospitals, long-term care facilities, alternate care sites and clinics within North America. Unlike the retail pharmacy market for oral products, the injectable pharmaceuticals marketplace is largely made up of end users who have relationships with group purchasing organizations, or GPOs, and/or specialty distributors who distribute products within a particular end-user market, such as oncology clinics. GPOs and specialty distributors generally enter into collective product purchasing agreements with pharmaceutical suppliers in an effort to secure more favorable drug pricing on behalf of their members.

We began in 1996 with an initial focus on U.S. marketing and distribution of generic pharmaceutical products manufactured by others. In June 1998, we acquired Fujisawa USA, Inc.'s generic injectable pharmaceutical business including manufacturing facilities in Melrose Park, Illinois and Grand Island, New York and our research and development facility in Melrose Park, Illinois. We also acquired additional assets in this transaction, including inventories, plant and equipment and abbreviated new drug applications that were approved by or pending with the U.S. Food and Drug Administration, or FDA.

We launched ABRAXANE™ on February 7, 2005 and hold the exclusive right to sell ABRAXANE™ in North America. ABRAXANE™ is a proprietary nanoparticle injectable oncology product that is a patented formulation of paclitaxel. Paclitaxel is the active ingredient in Taxol®, one of the world's top selling cancer drugs. ABRAXANE™, consists only of albumin-bound paclitaxel nanoparticles, is free of toxic solvents and demonstrated a superior response rate with an almost doubling of the reconciled target lesion response rate when compared with the solvent-based Taxol® in a prospectively randomized trial of 460 patients with metastatic breast cancer. Because it contains no toxic solvents, this next-generation taxane product enables the administration of 50% more chemotherapy with a well-tolerated safety profile, requires no routine premedication to prevent hypersensitivity reactions and can be given over a shorter infusion time using standard IV tubing.

We are a Delaware corporation that was formed in 2001 as successor to a California corporation formed in 1996. We are a majority owned subsidiary of American BioScience, Inc., a California corporation. At December 31, 2004, American BioScience owned 47,984,160 shares, or 67.9%, of our outstanding common stock.

### **Our Strategy**

Our goal is to expand upon our position as an industry leader in the development, manufacture, sale and distribution of injectable pharmaceutical products. The key elements of our strategy include:

- *Quickly develop the market for ABRAXANE™.* We believe that its efficacy, side-effect profile and ease of administration strongly position ABRAXANE™ against other taxanes. We intend to support the product with strong marketing and educational programs, expand into other licensed North American markets and pursue further clinical advances for the use of ABRAXANE™ in other indications and treatment regimens.
- *Continue to focus on product development and higher-margin opportunities.* We believe that significant opportunities for growth will continue to exist due to an increasing number of patent expirations for proprietary injectable pharmaceutical products. We will continue to target products where additional generic competition is likely to be limited because of complexities in product development, the need for specialized manufacturing capabilities and the need for raw materials that are difficult to obtain. Specific areas of interest include low molecular weight heparin and the potential for biologic generic products. We will continue to focus on product opportunities in the oncology, anti-infective and critical care markets, where we can utilize our manufacturing, development and regulatory skills.
- *Continue to focus on customer relationships.* We will continue to focus on growing our strong relationships with the leading GPOs and specialty distributors in the United States. Much of our growth to date has resulted from increased penetration of our existing products into hospitals that are members of the largest GPOs and our ability to develop and receive approval of new products in response to

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customer needs. Our products touch on virtually every aspect of acute patient care, including: emergency rooms, intensive care, cardiac care, oncology, pediatric, obstetric/gynecology, psychiatric, orthopedic and dialysis units and operating rooms. We are also aggressively targeting alternate care sites and pharmaceutical wholesale companies specializing in a particular therapeutic category. These relationships are key to ensuring a market for the products we develop and thus enable us to invest aggressively in new product development.

- *Pursue proprietary pharmaceutical product opportunities in our focus therapeutic areas.* We intend to acquire or license rights to proprietary injectable pharmaceutical products in our focus therapeutic areas, allowing us to enhance our market presence and visibility, as well as our revenue growth and profitability. We intend to take advantage of our manufacturing and marketing resources in oncology, anti-infectives and critical care by entering into development and marketing collaborations with companies that are developing proprietary products.
- *Complement internal growth with strategic acquisitions.* We believe opportunities exist for us to enhance our competitive position by acquiring products, technologies and companies with complementary products and technologies. We also intend to invest in or acquire additional manufacturing capacity to meet increased demand for our current and future products.

## Our Products

### *Generic Injectable Pharmaceuticals under Development*

Since 1998, when we acquired seven pending abbreviated new drug applications, or ANDAs, we have filed a total of 74 products with the FDA and received a total of 54 product approvals. We received 14 product approvals in 2004, including our first New Drug Application, or NDA, approval for tobramycin powder. We currently have 20 ANDAs pending with the FDA and over 50 product candidates under development across our oncology, anti-infective and critical care product categories. The following table highlights recent ANDA approvals:

### Summary of 2004 Approvals, Approved Filings and Launch Activity

Product	Brand Name	Indication	Approval Date	Launch Date
Amiodarone Hydrochloride	Cordarone I.V.®	Critical Care	10/27/04	Nov-04
Carboplatin (Liquid)	Paraplatin®	Oncology	10/18/04	Oct-04
Carboplatin (Lyophilized)	Paraplatin®	Oncology	5/22/02	Oct-04
Flumazenil	Romazicon®	Critical Care	10/13/04	Oct-04
Methylprednisolone Sodium	Solu-Medrol®	Critical Care	8/2/04	Aug-04
Esmolol Hydrochloride (t)	Brevibloc®	Critical Care	7/21/04	2005 (e)
Dimenhydrinate	Dramamine®	Critical Care	6/24/04	Aug-04
Tobramycin (NDA)	Nebcin®	Anti-Infective	7/15/04	Aug-04
Terbutaline Sulfate	Brethine®	Critical Care	5/28/04	Jun-04
Cladribine	Leustatin®	Oncology	5/27/04	Sep-04
Ciprofloxacin (t)	Cipro®	Anti-Infective	2/19/04	2006 (e)
Cytarabine	Cytosar-U®	Oncology	1/15/04	Mar-04
Piperacillin	Pipracil®	Anti-Infective	11/14/03	Jan-04
Fluconazole	Diflucan®	Critical Care	4/15/03	TBD
Vincristine	Oncovin®	Oncology	12/20/02	TBD
Bacitracin	Bacitracin®	Anti-Infective	1/3/02	Jun-04

(t) – tentative FDA approval, as of the date of this filing, pending only patent expiry and any subsequent exclusivity periods.

(e) – expected, actual launch could be delayed.

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### *Injectable Oncology Products*

We presently manufacture and market 17 injectable oncology products in 40 dosages and formulations. According to IMS Health, Inc., or IMS, a pharmaceutical market research firm, during 2004 we were the market leader for six of these products in terms of units sold in the United States, selling more units than the innovators and generic competitors. Net sales of our injectable oncology products increased 18% to \$95.9 million in 2004, representing 24% of our total net sales for that year.

Our oncology products include:

*Carboplatin.* Carboplatin is indicated for the initial treatment of advanced ovarian carcinoma in combination with other chemotherapeutic agents and for the palliative treatment of recurrent ovarian carcinoma after prior chemotherapy. Carboplatin is the generic equivalent of Bristol Myers Squibb Company's Paraplatin<sup>®</sup>. We launched the liquid and lyophilized versions of Carboplatin in October 2004.

*Pamidronate.* Pamidronate disodium is a bone-resorption inhibitor used to treat hypercalcemia associated with a malignancy, with or without bone metastases, and Paget's disease. Pamidronate disodium is the generic equivalent of Novartis Pharmaceuticals' Aredia<sup>®</sup>. We launched the liquid formulation of this product in May 2002 and offer the product in a unique plastic vial. IMS data indicates that we have been the liquid Pamidronate market leader in each year since its 2002 launch.

*Cisplatin.* Cisplatin is a chemotherapy agent used alone or in combination with other agents to treat metastatic testicular or ovarian cancer, Hodgkin's disease, non-Hodgkin's lymphoma, brain tumors, cancer of the nervous system and head, neck, bone, cervical, lung and bladder cancer. Bristol-Myers originally marketed cisplatin under the brand name Platinol<sup>®</sup>. Together with several other companies, we prevailed in a lawsuit invalidating Bristol-Myers Squibb patent covering this product in October 1999 and the FDA granted us 180 days of market exclusivity when we launched cisplatin in November 1999. We are currently one of five producers of cisplatin. According to IMS, we have been the market leader for cisplatin in terms of units sold for each of the past three years.

*Ifosfamide.* Ifosfamide is a chemotherapy drug used to treat germ cell testicular cancer and is often given in combination with Mesna. Bristol-Myers originally marketed ifosfamide under the brand name Ifex<sup>®</sup>. In response to customer requests, we were the first to offer individually packaged generic ifosfamide; our lyophilized form eliminated the need for the refrigerated storage required by the previous generic ifosfamide/mesna kit packaging. We launched ifosfamide in July 2002 with 180-day exclusivity; IMS data indicates that we captured approximately two-thirds of the ifosfamide individual vial market in 2004, up from 50% in 2003.

*Mesna.* Mesna is a cytoprotectant used to treat the side effects associated with certain chemotherapy drugs. Bristol-Myers originally marketed mesna under the brand name Mesnex<sup>®</sup>. Launched in May 2001, we were the first to market a generic version of mesna.

### *Injectable Anti-Infective Products*

We manufacture and market 17 injectable anti-infective products. According to IMS, we were the United States market leader for seven injectable anti-infective products in terms of units sold during 2004. Our injectable anti-infective products generated net sales of \$125.1 million in 2004, an increase of \$29.5 million, or 31% over the prior year and also represented 31% of 2004 total net sales.

We believe we offer one of the most comprehensive portfolios of injectable anti-infective products, including eight different classes of antimicrobials. We believe we are the only generic pharmaceutical company that owns and operates a dedicated manufacturing facility in the United States for cephalosporins. We currently are the only generic competitor offering first-generation, second-generation and third generation generic cephalosporins. The FDA requires dedicated facilities for the manufacture of cephalosporins. According to IMS,

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the 2004 markets for second and third generation cephalosporins were approximately \$136 million and \$770 million, respectively. Additionally, we launched three targeted antibiotic products in 2004: piperacillin, bacitracin and tobramycin powder.

Our anti-infective product line includes:

*Cefoxitin.* Cefoxitin is a second-generation cephalosporin with a broad range of anti-microbial activity. Cefoxitin is often used for gynecological infections, especially in peri-operative prophylaxis. Many infections caused by gram-negative bacteria resistant to some cephalosporins and penicillins respond to cefoxitin. Merck marketed the innovator product under the brand name Mefoxin<sup>®</sup>. According to IMS data, we captured a majority of the unit and dollar share of this market in North America in both 2003 and 2004.

*Vancomycin.* Vancomycin is an antibiotic used to treat some types of Staph, Strep or other infections, particularly in patients who are allergic to penicillins or cephalosporins. Eli Lilly originally marketed vancomycin under the brand name Vancocin<sup>®</sup>. IMS data indicates that we currently are one of two competitors for injectable vancomycin and the only generic competitor offering a 10-gram formulation of this antibiotic.

*Doxycycline.* Doxycycline is an antibiotic used to treat anthrax, Rocky Mountain Spotted Fever, typhus and mycoplasma pneumonia. Pfizer, Inc. originally marketed doxycycline under the brand name Vibramycin<sup>®</sup>. IMS indicates that we have been the North American market leader in both units and dollar value sold for each of the past three years.

*Cefotaxime.* Cefotaxime is a broad spectrum antibiotic in the third-generation cephalosporin class of antibiotics. It is used to treat intra-abdominal infections such as peritonitis, central nervous system infections including meningitis, lower respiratory tract, genitourinary, and gynecological infections, bacteremia and septicemia, and infections of the skin, bone and joints. Abbott Laboratories licensed the marketing rights from the innovator under the brand name Claforan<sup>®</sup>. We initially introduced cefotaxime on a limited basis in September 2001, and conducted a full-scale launch of the product in February 2002. We are the only manufacturer and marketer of generic cefotaxime in the United States.

*Gentamicin.* Gentamicin is an antibiotic used to treat endocarditis, septicemia and bacterial, bone, respiratory tract, soft tissue, urinary tract and other infections. Schering-Plough originally marketed this product under the brand name Garamycin<sup>®</sup>. We currently are one of three competitors for gentamicin. According to IMS, we sold the second largest number of units of injectable gentamicin in each of 2004 and 2003.

### *Injectable Critical Care Products*

We manufacture and market more than 55 injectable critical care products. According to IMS, 14 and 12 of our critical care products held first or second position, respectively, in the United States market in terms of units sold in 2004. Our critical care product line encompasses a wide range of products essential to hospitals and clinics, ranging from diluents, to heart medications, to steroidal products to sedatives. Our injectable critical care products generated net sales of \$178.2 million in 2004, representing 44% of our total net sales for that year.

Our critical care products include:

*Heparin.* Injectable heparin is a blood thinner used to prevent and treat blood clotting, especially during and after surgery. We manufacture one of the most comprehensive lines of injectable therapeutic heparin. We currently are one of four competitors for injectable heparin. According to IMS, for each of the past three years we have been the North American market leader, in both number of units and dollar value, of therapeutic injectable heparin sold.

*Oxytocin.* Oxytocin is used to induce labor at term and control postpartum bleeding. Wyeth-Ayerst originally marketed oxytocin under the brand name Pitocin<sup>®</sup>. We are currently the only domestic manufacturer of generic oxytocin, and, according to IMS, we were the market leader for oxytocin in terms of units sold in 2004, with an approximate 95% share of the combined branded and generic markets.

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### **Proprietary Injectable Product**

*ABRAXANE™, a proprietary injectable oncology product*

We hold the exclusive North American rights to market and sell ABRAXANE™, a proprietary nanoparticle injectable oncology product that is a patented formulation of paclitaxel. Paclitaxel is the active ingredient in Taxol®, one of the world's top selling cancer drugs. In January 2005, we announced that American BioScience's New Drug Application, or NDA, for ABRAXANE™ had been approved by the U.S. Food and Drug Administration, or FDA, and we launched the product on February 7, 2005. ABRAXANE™, consists only of albumin-bound paclitaxel nanoparticles, is free of toxic solvents and demonstrated a superior response rate with an almost doubling of the reconciled target lesion response rate when compared with the solvent-based Taxol® in a prospectively randomized trial of 460 patients with metastatic breast cancer. Because it contains no toxic solvents, this next-generation taxane product enables the administration of 50% more chemotherapy with a well-tolerated safety profile, requires no routine premedication to prevent hypersensitivity reactions and can be given over a shorter infusion time using standard IV tubing.

Many oncology drugs, including paclitaxel, are water insoluble and thus have historically required toxic solvents to formulate the drugs for injection. Taxol® and its generic equivalents contain the toxic solvent Cremophor. The toxicity of Cremophor limits the dose of Taxol® that can be administered, potentially limiting the efficacy of the drug. Furthermore, patients receiving Taxol® require pre-medication with steroids to prevent the toxic side effects associated with Cremophor and, in some cases, require a growth factor such as G-CSF to overcome low white blood cell levels resulting from chemotherapy. The approved dose of Taxol® is 135–175 mg/m<sup>2</sup>, administered over three to 24 hours using specialized intravenous tubing. Despite the difficulties associated with administration and serious dose-limiting toxicities, IMS data indicates that the 2004 U.S. market for paclitaxel-based drugs approximated \$1.0 billion. ABRAXANE™ utilizes a proprietary, patented nanoparticle drug delivery technology to encapsulate paclitaxel in albumin, a human protein found in blood, and is not formulated with Cremophor. We believe the nanoparticle more easily permeates the tumor, rapidly carrying more paclitaxel to the cancer cells and at the same time allowing less drug indiscriminately into normal, healthy cells. Additionally, ABRAXANE™ provides several advantages over Taxol® and its generic equivalents, including: avoiding the need for premedication to prevent hypersensitivity reactions: reducing or eliminating the need for G-CSF support: and allowing for more rapid infusion without the need for specialized intravenous tubing.

#### *Phase III Clinical Trial Results*

The FDA's approval of ABRAXANE™ in January 2005 was, in part, based on the results of the randomized, controlled Phase III clinical trial in patients with metastatic breast cancer comparing the investigational product ABRAXANE™ to the Cremophor® solvent-based TAXOL®. A detailed analysis of the study was presented at the San Antonio Breast Cancer Symposium held in San Antonio, Texas in December 2003. This randomized controlled Phase III clinical trial was designed to compare the safety and efficacy of 260 mg/m<sup>2</sup> of ABRAXANE™ to 175 mg/m<sup>2</sup> of Taxol® administered every three weeks in patients with metastatic breast cancer. In this trial, ABRAXANE™ was infused over 30 minutes without steroid pretreatment at a higher dose than Taxol®, which requires steroid therapy and infusion over three hours.

In this Phase III trial, patients with metastatic breast cancer receiving the solvent-free nanoparticle paclitaxel, ABRAXANE™ (n=229 patients) achieved almost a doubling of the tumor response rate when compared to those patients receiving Bristol-Myers Squibb's Taxol® (n=225). In the overall patient population, median survival for those patients receiving ABRAXANE™ was 10 weeks longer (65.0 weeks v. 55.7 weeks) than for patients receiving Taxol but this difference did not reach statistical significance. However there was a significant prolongation in survival (p=0.016) in patients receiving ABRAXANE™ in the second-line or greater setting as compared to those receiving Taxol (56.4 weeks vs. 46.7 weeks). In this group, there was a 29% reduction in the risk of death (i.e., hazard ratio of 0.71) for patients who received ABRAXANE™ compared to those who received Taxol®.

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The Phase III study demonstrated potentially important advantages of ABRAXANE™ over Taxol® as a treatment for metastatic breast cancer patients, based on:

- higher response rates;
- longer time to tumor progression;
- absence of severe hypersensitivity reactions without the need for premedication;
- less neutropenia despite a higher dose infused over a shorter period of 30 minutes; and,
- a rapid recovery from sensory neuropathy compared with Taxol®, albeit with a somewhat higher incidence consistent with the higher dosage of paclitaxel administered.

Specifically, the results reported were as follows:

- A significantly higher Overall Tumor Response Rate was noted in patients receiving ABRAXANE™ (33%) versus Taxol® (19%), ( $p=0.001$ ). Similarly, analysis of the Target Lesion Response Rate showed significantly higher anti-tumor activity ( $p<0.001$ ) with ABRAXANE™;
- In patients receiving chemotherapy for metastatic breast cancer for the first time (first-line patients), a significantly higher tumor response was also noted, with 42% of ABRAXANE™ patients ( $n=97$ ) responding to the therapy compared with a 27% response rate in patients ( $n=89$ ) receiving Taxol® ( $p=0.029$ );
- Similarly, the response rates with ABRAXANE™ were higher, and statistically significant, when analyzed in those patients who had failed prior chemotherapy, and in patients with poor prognostic indicators such as in those with liver metastases (26%,  $n=92$  vs. 13%,  $n=97$ ) and lung metastases (43%,  $n=74$  vs. 25%,  $n=79$ );
- A longer time to tumor progression was noted in patients receiving ABRAXANE™, with a median of 21.9 weeks versus a median progression time of 16.1 weeks after Taxol®, ( $p=0.030$ );
- 98% of cycles of ABRAXANE™ were administered without premedication to prevent hypersensitivity reactions and no evidence of severe hypersensitivity reactions were noted in any of these patients thus confirming the ability to safely administer this solvent-free paclitaxel without the need for premedication. In contrast, 95% of the doses of Taxol® were administered with steroids and antihistamines, and still these patients showed a significantly higher incidence of flushing than those patients receiving ABRAXANE™ without premedication;
- Both treatments were well tolerated with 98% of patients receiving the planned dose on both arms; the mean total paclitaxel dose delivered with ABRAXANE™ was 1459mg per patient per m2 and 909mg per patient per m2 with Taxol®;
- Consistent with this higher dose of paclitaxel delivered with ABRAXANE™, the incidence of Grade 3 sensory neuropathy was 10% versus 2% in the patients receiving Taxol® ( $p<0.001$ ). The Grade 3 sensory neuropathy resolved rapidly in the ABRAXANE™ patients within a median of 22 days and was thus easily managed. In contrast, and consistent with current clinical experience, recovery of the neuropathy after Taxol® administration was significantly prolonged with a median of 79 days ( $p=0.028$ ). This finding suggests that it is possible, consistent with preclinical studies in the literature, that the Cremophor component of Taxol® may be responsible for structural damage (demyelination) to the nerve fibers resulting in prolonged neuropathy, while neuropathy due to paclitaxel alone is transient with rapid resolution. There were no reports of Grade 4 sensory neuropathy or severe motor neuropathy in either arm;
- Despite the higher dose of paclitaxel delivered, there was significantly less Grade 4 neutropenia with ABRAXANE™ (9%) compared to Taxol® (22%), providing the first clinical evidence that Cremophor may contribute to bone marrow damage and loss of white blood cells;
- Fluid retention was infrequent in both arms and there were no septic deaths in the study.

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### *Ongoing Clinical Studies*

In addition to the aforementioned Phase III clinical trial, approximately 40 clinical studies of ABRAXANE™ in various indications and settings are planned or underway, including:

- A Phase II trial to explore a weekly dosing regimen of ABRAXANE™ in patients with metastatic breast cancer in which prior taxane therapy has failed,
- a U.S. single-center, dose escalation Phase I/II clinical trial to evaluate the safety and anti-tumor activity of ABRAXANE™ in advanced, non-small cell lung cancer, and
- a multi-center Phase II trial to evaluate the safety, tolerability and anti-tumor effect of ABRAXANE™ in first and second-line patients with metastatic melanoma.

### *License and Manufacturing Agreements*

We hold the exclusive North American marketing rights and worldwide manufacturing rights for ABRAXANE™. The FDA approved ABRAXANE™, for the filed indication on January 7, 2005 and ABRAXANE™ was launched on February 7, 2005. ABRAXANE™ is licensed from American BioScience, which is responsible for conducting the clinical studies of and obtaining regulatory approval for ABRAXANE™.

In November 2001, we signed a perpetual license agreement with American BioScience under which we acquired the exclusive rights to market and sell ABRAXANE™ in North America for indications relating to breast, lung, ovarian, prostate and other cancers. Under the agreement, we made an initial payment to American BioScience of \$60.0 million and committed to future milestone payments contingent upon achievement of specified regulatory, publication and sales objectives for licensed indications. American BioScience is responsible for conducting clinical studies in support of ABRAXANE™ and for substantially all costs associated with the development and obtaining regulatory approval for ABRAXANE™, except that we provided \$2.0 million of ABRAXANE™ for use in clinical trials, the cost of which we charged to research and development expense in 2001. Any profit, as defined in the license agreement, resulting from our sales of ABRAXANE™ will be shared equally between American BioScience and us, following the recapture of half of the pre-launch sales, marketing and pre-production start-up costs we have incurred.

The terms of the license agreement were negotiated to reflect the value of the licensed product rights acquired, then in late-stage development, American BioScience's remaining obligation to complete the NDA filing and the potential sales of the product under licensed clinical indications. The license agreement was a product of several months of extensive negotiation with American BioScience involving outside counsel, investment banks and a nationally recognized valuation firm. Based upon the analysis and recommendations of our advisors, we believe that the overall terms of the agreement were fair to us, including in comparison to similar licenses between unrelated parties. The agreement was unanimously approved by the disinterested members of our Board of Directors, with those directors who also have an affiliation with American BioScience recusing themselves from the vote. There are no restrictions on how American BioScience would use payments made under the license agreement and we understand such payments have been and will be used both to fund the development of ABRAXANE™ in relation to our licensed product rights and for other purposes.

In December 2001, in conjunction with our initial public offering, we recorded an initial payment due American BioScience of \$60.0 million. In our financial statements, the license agreement was accounted for as an asset contributed by a principal shareholder using the shareholder's historical cost basis, which was zero, and the \$60.0 million payment was accounted for as a distribution of stockholders' equity. For income tax purposes, the payment was recorded as an asset and is being amortized over a 15-year period. Because there was no corresponding charge to income, the income tax benefit of this payment is being credited to stockholders' equity as realized.

Under the license agreement, American BioScience earned milestone payments upon the filing and approval of ABRAXANE™ for the metastatic breast cancer indication. The first such milestone of \$10.0 million was achieved in May, 2004 when the FDA accepted American BioScience's NDA for the metastatic breast cancer

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indication. This payment was expensed and paid in the second quarter of 2004. The FDA then approved ABRAXANE™ for the filed indication in January 2005, triggering a \$15.0 million milestone payment in the first quarter of 2005 which will be capitalized and amortized over the expected life of the product, subject to periodic review for impairment.

Regulatory and publication achievements related to other licensed indications under study, including lung, ovarian and prostate cancers will trigger further milestone payments to American BioScience. Such payments generally total \$17.5 million per agreed indication. As with the indication of breast cancer, those payments earned prior to FDA approval for each indication will be expensed, while amounts earned upon FDA approval of those indications will be capitalized and amortized over the expected life of the product. We have the option not to make one or more of the milestone payments tied to certain indications under study if sales of the product do not meet specified levels.

Upon achievement of major annual one-time ABRAXANE™ sales milestones, we are required to make additional payments which, in the aggregate, could total \$110.0 million should annual ABRAXANE™ sales exceed \$1.0 billion. The first sales milestone payment of \$10.0 million would be triggered upon achievement of annual calendar year ABRAXANE™ sales in excess of \$200.0 million and the second sales milestone of \$20.0 million upon the achievement of annual calendar year sales in excess of \$400.0 million. Any future sales-based milestone payments will be expensed in the period in which the sales milestone is achieved.

Under the license agreement, profit on our sales of ABRAXANE™ in North America will be shared equally between American BioScience and us. The license agreement defines profit as ABRAXANE™ net sales less cost of goods sold, selling expenses (including pre-launch production and other expenses which we have expensed as incurred, but which will be charged against first profit under the agreement) and an allocation of related general and administrative expenses. We will expense American BioScience's share of profit earned in our statements of income as an element of cost of sales. Any costs and expenses related to product recalls and product liability claims generally will be split equally between American BioScience and us and expensed as incurred. Pursuant to an agreement that we have with American BioScience, certain costs of any unsaleable ramp-up inventory of ABRAXANE™ that was manufactured in preparation for its launch will be shared equally between us and American BioScience.

In November 2001, along with the license agreement for ABRAXANE™, we also entered into a manufacturing agreement with American BioScience under which we agreed to manufacture ABRAXANE™ for American BioScience and its licensees for sales outside North America. Under this agreement, we have the right to manufacture ABRAXANE™ for sales worldwide. For sales outside of our licensed territories, we will charge American BioScience and its licensees a customary margin on our manufacturing costs based on whether the product will be used for clinical trials or commercial sale. The initial term of this agreement is ten years and may be extended for successive two-year terms by American BioScience.

## **Research and Development**

We have approximately 73 employees dedicated to product development, including more than 35 employees with Ph.D.s, who have expertise in areas such as pharmaceutical formulation, analytical chemistry and drug delivery. We own and operate a 140,000 square foot research and development facility in Melrose Park, Illinois. The Melrose Park facility is currently undergoing a major renovation, reconfiguration and expansion to enhance our development capabilities. We have made, and will continue to make, substantial investment in research and development. Research and development costs for the fiscal year ended December 31, 2004 totaled \$25.8 million, including \$8.0 million related to the development of ABRAXANE™ manufacturing capabilities.

When developing new products, we consider a variety of factors, including:

- potential pricing and gross margins
- existing and potential market size

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- high barriers to entry
- patent expiration date
- our manufacturing capabilities and access to raw materials
- potential development and competitive challenges
- whether these products complement our existing products and the opportunity to leverage these products with the development of additional products

### **Sales and Marketing**

Our core generic products are primarily marketed by a dedicated sales force to hospitals, long-term care facilities, alternate care sites, clinics and doctors who administer injectable products in their offices. Many purchases by these buyers are made through arrangements with GPOs, which negotiate collective purchasing agreements on behalf of their members, or through specialty distributors, which specialize in particular therapeutic categories such as oncology. We sell to members of all of the major GPOs in the United States, which we believe collectively represent over 95% of all hospital-based pharmaceutical purchasers in the United States. We also sell products to the leading specialty distributors. We believe we have access to nearly 100% of the buyers of injectable products in the United States. Our core generic sales force is comprised of approximately 45 field sales and national accounts professionals, supported by our customer service and sales support groups. Our representatives typically have substantial injectable pharmaceutical sales experience in the geographic region in which they operate.

In late 2003, we formed the Abraxis Oncology division to prepare for, and market and sell, our proprietary oncology product ABRAXANE™ upon its launch. The dedicated Abraxis Oncology sales and marketing group is specifically targeted on key segments of the oncology market: specifically, leading oncologists, cancer centers and the oncology distribution channel. During 2004, Abraxis Oncology finalized the marketing strategy, developed marketing and sales tools, gained a thorough understanding of the market and educated thought leaders on the nanoparticle technology underlying ABRAXANE™ and the new class of drugs it represents. Presently, Abraxis Oncology is comprised of approximately 108 individuals including an 80 member sales force and marketing and medical support staff.

We currently derive, and expect to continue to derive, a large percentage of our revenue from customers that are members of a small number of GPOs. Currently, fewer than ten GPOs control a large majority of sales to hospital customers. We have purchasing arrangements with the major GPOs in the United States, including AmeriNet, Inc., Broadlane Healthcare Corporation, Consorta, Inc., MedAssets Inc., Novation, LLC, Owen Healthcare, Inc., PACT, LLC, Premier Purchasing Partners, LP, International Oncology Network, or ION, National Oncology Alliance, or NOA and U.S. Oncology, Inc.. In order to maintain these relationships, we believe we need to be a reliable supplier, offer a broad product line, remain price competitive, comply with FDA regulations and provide high-quality products. Our GPO agreements are typically multi-year in duration and may be terminated on short notice.

Our international sales, outside the U.S. and Canada, are approximately 1% of our total net sales.

### **Competition**

We face competition in our core generic business from major, brand name pharmaceutical companies as well as generic manufacturers such as Hospira, Bedford Laboratories, Baxter Laboratories (including Elkin-Sinn), Sico Inc. (recently acquired by Teva), Mayne Pharma (Faulding Pharmaceuticals) and increased competition from new, overseas competitors.

Revenue and gross profit derived from sales of generic pharmaceutical products tend to follow a pattern based on regulatory and competitive factors. As patents for brand name products and related exclusivity periods expire, the first generic pharmaceutical manufacturer to receive regulatory approval for generic versions of these

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products is generally able to achieve significant market penetration and higher margins. As competing generic manufacturers receive regulatory approvals on similar products, market share, revenue and gross profit typically decline. The level of market share, revenue and gross profit attributable to a particular generic pharmaceutical product is normally related to the number of competitors in that product's market and the timing of that product's regulatory approval and launch in relation to competing approvals and launches. We continue to develop and introduce new products in a timely and cost-effective manner and identify niche products with significant barriers to entry in order to maintain our revenue and gross margins.

We believe that ABRAXANE™ competes, directly or indirectly, with the primary taxanes in the market place, including Bristol Myers' Taxol® and its generic equivalents, Aventis' Taxotere® and other cancer therapies. Many pharmaceutical companies have developed and are marketing, or are developing, alternative formulations of paclitaxel and other cancer therapies that may compete directly or indirectly with ABRAXANE™.

### **Regulatory Considerations**

Proprietary and generic prescription pharmaceutical products 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 the products under the Federal Food Drug and Cosmetic Act and the Public Health Services Act, and by comparable agencies in foreign countries. FDA approval is required before any dosage form of any drug, including a generic equivalent of a previously approved drug, can be marketed in the United States. All applications for FDA approval must contain information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control.

### **Generic Drug Approval**

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, established abbreviated FDA approval procedures for those proprietary drugs that are no longer protected by patents and which are shown to be equivalent to previously approved proprietary drugs. Approval to manufacture these drugs is obtained by filing an abbreviated new drug application, or an ANDA. An ANDA is a comprehensive submission that must contain data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. As a substitute for clinical studies, the FDA may require data indicating that the ANDA drug formulation is equivalent to a previously approved proprietary drug. In order to obtain an ANDA approval of strength or dosage form that differs from the referenced brand name drug, an applicant must file and have granted an ANDA Suitability Petition. A product is not eligible for ANDA approval if it is not determined by the FDA to be equivalent to the referenced brand name drug or if it is intended for a different use. However, such a product might be approved under a New Drug Application, or an NDA, with supportive data from clinical trials.

One advantage of the ANDA approval process is that an ANDA applicant generally can rely upon equivalence data in lieu of conducting pre-clinical testing and clinical trials to demonstrate that a product is safe and effective for its intended use. We generally file ANDAs to obtain approval to manufacture and market our generic products. No assurance can be given that ANDAs submitted for our products will receive FDA approval on a timely basis, if at all.

### **New Drug Approval**

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

- completion of pre-clinical laboratory and animal testing
- submission of an investigational new drug application, or IND, which must become effective before trials may begin

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- 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, or NDA

Clinical trials are typically conducted in three sequential phases that may overlap. These phases generally include:

- Phase I during which the drug is introduced into healthy human subjects or, on occasion, patients, and generally is tested for safety, stability, dose tolerance and metabolism
- Phase II during which the drug is introduced into a limited patient population to determine the efficacy of the product in specific targeted diseases, to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks
- Phase III during which the clinical trial is expanded to a more diverse patient group in geographically dispersed trial sites to further evaluate clinical efficacy, optimal dosage and safety

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 belief that the subjects are being exposed to an unacceptable health risk.

The results of product development, preclinical animal 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 on the basis of the submission made or disapprove the NDA if applicable FDA regulatory criteria are not satisfied. The FDA may also require additional clinical data. Under certain circumstances, drug sponsors may obtain approval pursuant to Section 505(b)(2) of the Federal Food, Drug & Cosmetic Act based in part upon literature or an FDA finding and/or effectiveness for another approved product, even where the products are not duplicates in terms of chemistry and bioequivalence. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

Satisfaction of FDA pre-market approval requirements typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. 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. 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. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

### **Manufacturing**

Our manufacturing facilities are located in Melrose Park, Illinois, Grand Island, New York and Barbengo, Switzerland. These facilities, which include dedicated cephalosporin powder filling, liquid filling line and oncolytic manufacturing suites, have in the aggregate approximately 567,000 square feet of manufacturing, packaging, laboratory, office and warehouse space.

We can produce a broad range of dosage formulations, including lyophilized products, liquids, both aseptically filled and terminally sterilized, and powders. Additionally, we believe that we have established the only commercial scale protein-engineered nanoparticle manufacturing capacity in the United States. We currently produce approximately 200 million vials of product per year.

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In addition to manufacturing, we have fully integrated manufacturing support systems, including quality assurance, quality control, regulatory affairs and inventory control. These support systems enable us to maintain high standards of quality for our products and simultaneously deliver reliable services and goods to our customers on a timely basis.

We are required to comply with the applicable FDA manufacturing requirements contained in the FDA's current Good Manufacturing Practice, or cGMP, regulations. cGMP regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation. Our manufacturing facilities must meet cGMP requirements to permit us to manufacture our products. We are subject to the periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the Drug Enforcement Administration and other authorities to assess our compliance with applicable regulations.

Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

### **Raw Materials**

The manufacture of our products requires raw materials and other components that must meet stringent FDA requirements. Some of these raw materials and other components are currently available only from a limited number of sources. Additionally, our regulatory approvals for each particular product denote the raw materials and components, and the suppliers for such materials, we may use for that product. Even when more than one supplier exists, we may elect to list, and in some cases have only listed, one supplier in our applications with the FDA. Any change in or addition of a supplier not previously approved must then be submitted through a formal approval process with the FDA. From time to time, it is necessary to maintain increased levels of certain raw materials due to the anticipation of raw material shortages or in response to market opportunities.

### **Intellectual Property**

Our success depends on our ability to operate without infringing the patents and proprietary rights of third parties. We cannot determine with certainty whether patents or patent applications of other parties will materially affect our ability to make, use or sell any products. A number of pharmaceutical companies, biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover aspects of our or our licensors' products, product candidates or other technologies.

We rely on trade secrets, unpatented proprietary know-how, continuing technological innovation and, in some cases, patent protection to preserve our competitive position. As of December 31, 2004, we owned several patents issued by the U.S. Patent and Trademark Office, and have additional patent applications pending, relating to our products including certain manufacturing methods. In addition, ABRAXANE<sup>™</sup>, and the technology surrounding ABRAXANE<sup>™</sup>, is covered by a number of issued patents owned by American BioScience and licensed by us relating to composition of matter, method of use and method of preparation.

Intellectual property protection is highly uncertain and involves complex legal and factual questions. Our patents and those for which we have or will license rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us.

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Third-party patent applications and patents could reduce the coverage of the patents licensed, or that may be licensed to or owned by us. If patents containing competitive or conflicting claims are issued to third parties, we may be enjoined from commercialization of products or be required to obtain licenses to these patents or to develop or obtain alternative technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or our licensors.

Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party's proprietary rights. U.S. Patent Office interference proceedings may be necessary if we and another party both claim to have invented the same subject matter. We could incur substantial costs and our management's attention would be diverted if:

- patent litigation is brought by third parties
- we are party to or participate in patent suits brought against or initiated by our licensors
- we initiate similar suits
- we are party to or participate in an interference proceeding

In addition, we may not prevail in any of these actions or proceedings.

### **Employees**

As of December 31, 2004, we had a total of 1,381 full-time employees, of which 73 were engaged in research and development, 301 were in quality assurance and quality control, 711 were in manufacturing, 175 were in sales and marketing and 121 were in administration and finance. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have not experienced any work stoppage and consider our relations with our employees to be good.

### **Environment**

We believe that our operations comply in all material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our earnings or competitive position.

### **Available Information**

Our Internet address is [www.appdrugs.com](http://www.appdrugs.com). Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to such reports, are available free of charge on our website as soon as reasonably practical after they are electronically filed or furnished to the SEC. The information found on our website shall not be deemed incorporated by reference by any general statement into any filing under the Securities Act of 1933 or under the Securities Exchange Act of 1934, except to the extent we specifically incorporate the information found on our website by reference, and shall not be deemed filed under such Acts.

### **Factors That May Affect Future Results of Operations**

**If ABRAXANE™ does not achieve strong market acceptance, our future profitability could be adversely affected and we would be unable to recoup the investments made to license and commercialize this product.**

In connection with our agreement to license ABRAXANE™ from American BioScience, we paid a substantial upfront licensing fee and have committed to make milestone payments and to split any profit on

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ABRAXANE™. Also, in anticipation of the 2005 approval and launch of ABRAXANE™ we invested significantly and expanded our marketing, sales and manufacturing staff, invested in paclitaxel raw material and manufactured \$9.3 million of ABRAXANE™ finished product. The inability to successfully manufacture, market and commercialize ABRAXANE™ could cause us to lose some or all of the investment we have made to license and commercialize this product.

American BioScience is responsible for conducting clinical trials and obtaining necessary regulatory approvals prior to commercialization of ABRAXANE™ and for the use of ABRAXANE™ in other indications and settings. The amount and timing of resources American BioScience devotes to develop ABRAXANE™ is not within our control. Additionally, any breach or termination of the ABRAXANE™ license agreement could adversely affect, delay or stop the commercialization of ABRAXANE™.

The results from clinical, pre-clinical studies and early clinical trials conducted to date may not be predictive of results to be obtained in later clinical trials, including those ongoing at present. Further, the commencement and completion of clinical trials may be delayed by many factors that are beyond our control, including:

- slower than anticipated patient enrollment
- difficulty in finding and retaining patients fitting the trial profile
- adverse events occurring during the clinical trials

Although approved by the FDA, ABRAXANE™ may not generate sales sufficient to recoup the investments made to license and commercialize the product. Additionally, the success of ABRAXANE™ in the Phase III trial for metastatic breast cancer may not be representative of the future clinical trial results for ABRAXANE™ with respect to other clinical indications. Further, a number of pharmaceutical companies are working to develop alternative formulations of paclitaxel and other cancer drugs and therapies, any of which may compete directly or indirectly with ABRAXANE™ and which might adversely affect the commercial success of ABRAXANE™.

### **If we are unable to develop and commercialize new products, our financial condition will deteriorate.**

Profit margins for a pharmaceutical product generally decline as new competitors enter the market. As a result, our future success will depend on our ability to commercialize the product candidates we are currently developing, as well as develop new products in a timely and cost-effective manner. We have over 50 new product candidates under development. Successful development and commercialization of our product candidates will require significant investment in many areas, including research and development and sales and marketing, and we may not realize a return on those investments. In addition, development and commercialization of new products are subject to inherent risks, including:

- failure to receive necessary regulatory approvals
- difficulty or impossibility of manufacture on a large scale
- prohibitive or uneconomical costs of marketing products
- inability to secure raw material or components from third-party vendors in sufficient quantity or quality or at a reasonable cost
- failure to be developed or commercialized prior to the successful marketing of similar or superior products by third parties
- lack of acceptance by customers
- impact of authorized generic competition
- infringement on the proprietary rights of third parties

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- grant of new patents for existing products may be granted, which could prevent the introduction of newly-developed products for additional periods of time
- grant to another manufacturer by the FDA of a 180-day period of marketing exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, as patents or other exclusivity periods for brand name products expire

The timely and continuous introduction of new products is critical to our business. Our financial condition will deteriorate if we are unable to successfully develop and commercialize new products.

### **If sales of our key products decline, our business may be adversely affected.**

Our top ten products comprised approximately 51% of our 2004 net sales. Our key products could lose market share or revenue due to numerous factors, many of which are beyond our control, including:

- lower prices offered on similar products by other manufacturers
- substitute or alternative products or therapies
- development by others of new pharmaceutical products or treatments that are more effective than our products
- introduction of other generic equivalents or products which may be therapeutically interchanged with our products
- interruptions in manufacturing or supply
- changes in the prescribing practices of physicians
- changes in third-party reimbursement practices
- migration of key customers to other manufacturers or sellers

Any factor adversely affecting the sale of our key products may cause our revenues to decline.

### **If we or our suppliers are unable to comply with ongoing and changing regulatory standards, sales of our products could be delayed or prevented.**

Virtually all aspects of our business, including the development, testing, manufacturing, processing, quality, safety, efficacy, packaging, labeling, record-keeping, distribution, storage and advertising of our products and disposal of waste products arising from these activities, are subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA. Our business is also subject to regulation in foreign countries. Compliance with these regulations is costly and time-consuming.

Our manufacturing facilities and procedures and those of our suppliers are subject to ongoing regulation, including periodic inspection by the FDA and foreign regulatory agencies. For example, manufacturers of pharmaceutical products must comply with detailed regulations governing current good manufacturing practices, including requirements relating to quality control and quality assurance. We must spend funds, time and effort in the areas of production, safety, quality control and quality assurance to ensure compliance with these regulations. We cannot assure that our manufacturing facilities or those of our suppliers will not be subject to regulatory action in the future.

Our products generally must receive appropriate regulatory clearance before they can be sold in a particular country, including the United States. We may encounter delays in the introduction of a product as a result of, among other things, insufficient or incomplete submissions to the FDA for approval of a product, objections by another company with respect to our submissions for approval, new patents by other companies, patent challenges by other companies which result in a 180-day exclusivity period, and changes in regulatory policy

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during the period of product development or during the regulatory approval process. The FDA has the authority to revoke drug approvals previously granted and remove from the market previously approved products for various reasons, including issues related to current good manufacturing practices for that particular product or in general. We may be subject from time to time to product recalls initiated by us or by the FDA. Delays in obtaining regulatory approvals, the revocation of a prior approval, or product recalls could impose significant costs on us and adversely affect our ability to generate revenue.

Our inability or the inability of our suppliers to comply with applicable FDA and other regulatory requirements can result in, among other things, warning letters, fines, consent decrees restricting or suspending our manufacturing operations, delay of approvals for new products, injunctions, civil penalties, recall or seizure of products, total or partial suspension of sales and criminal prosecution. Any of these or other regulatory actions could materially adversely affect our business and financial condition.

### **The manufacture of our products is highly exacting and complex, and if we or our suppliers encounter production problems, our business may suffer.**

All of the products we make are sterile, injectable drugs. We also purchase some such products from other companies. Additionally, the process for manufacturing the nano-particle product ABRAXANE™ is relatively new and unique. The manufacture of all our products is highly exacting and complex, due in part to strict regulatory requirements and standards which govern both the manufacture of a particular product and the manufacture of these types of products in general. Problems may arise during their manufacture due to a variety of reasons including equipment malfunction, failure to follow specific protocols and procedures, and environmental factors. If problems arise during the production of a batch of product, that batch of product may have to be discarded. This could, among other things, lead to loss of the cost of raw materials and components used, lost revenue, time and expense spent in investigating the cause, and, depending on the cause, similar losses with respect to other batches or products. If such problems are not discovered before the product is released to the market, recall costs may also be incurred. To the extent we experience problems in the production of our pharmaceutical products, this may be detrimental to our business, operating results and reputation.

### **Our markets are highly competitive and, if we are unable to compete successfully, our revenue will decline and our business will be harmed.**

The markets for injectable pharmaceutical products are highly competitive, rapidly changing and undergoing consolidation. Most of our products are generic injectable versions of brand name products that are still being marketed by proprietary pharmaceutical companies. The first company to market a generic product is often initially able to achieve high sales, profitability and market share with respect to that product. Prices, revenue and market size for a product typically decline, however, as additional generic manufacturers enter the market.

We face competition from major, brand name pharmaceutical companies as well as generic manufacturers such as Hospira, Bedford Laboratories, Baxter Laboratories (including Elkin-Sinn), Sicor Inc. (recently acquired by Teva) and Mayne Pharma (Faulding Pharmaceuticals) and, in the future, increased competition from new, foreign competitors. Smaller and foreign companies may also prove to be significant competitors, particularly through collaboration arrangements with large and established companies. Many of our competitors have significantly greater research and development, financial, sales and marketing, manufacturing, regulatory and other resources than us. As a result, they may be able to devote greater resources to the development, manufacture, marketing or sale of their products, receive greater resources and support for their products, initiate or withstand substantial price competition, more readily take advantage of acquisition or other opportunities, or otherwise more successfully market their products.

Any reduction in demand for our products could lead to a decrease in prices, fewer customer orders, reduced revenues, reduced margins, reduced levels of profitability, or loss of market share. These competitive pressures could adversely affect our business and operating results.

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### **We face uncertainty related to pricing and reimbursement, particularly as it relates to ABRAXANE™, and health care reform.**

In both domestic and foreign markets, sales of our products, particularly ABRAXANE™, will depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers, health maintenance organizations and other health care-related organizations. Reimbursement by such payors is presently undergoing reform and there is significant uncertainty at this time how this will affect sales of certain pharmaceutical products, including ABRAXANE™.

Medicare, Medicaid and other reimbursement legislation or programs govern drug coverage and reimbursement levels in the United States. Federal law requires all pharmaceutical manufacturers to rebate a percentage of their revenue arising from Medicaid-reimbursed drug sales to individual states. Generic drug manufacturers' agreements with federal and state governments provide that the manufacturer will remit to each state Medicaid agency, on a quarterly basis, 11% of the average manufacturer price for generic products marketed and sold under abbreviated new drug applications covered by the state's Medicaid program. For proprietary products, which are marketed and sold under new drug applications, manufacturers are required to rebate the greater of (a) 15.1% of the average manufacturer price or (b) the difference between the average manufacturer price and the lowest manufacturer price for products sold during a specified period.

Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, rules and regulations designed to contain or reduce the cost of health care. Existing regulations that affect the price of pharmaceutical and other medical products may also change before any of our products are approved for marketing. Cost control initiatives could decrease the price that we receive for any product we develop in the future. In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services and litigation has been filed against a number of pharmaceutical companies in relation to these issues. Additionally, significant uncertainty exists as to the reimbursement status of newly approved injectable pharmaceutical products, including ABRAXANE™. Our products may not be considered cost effective or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an adequate return on our investment.

### **If we are unable to maintain our key customer arrangements, sales of our products and revenue would decline.**

Almost all injectable pharmaceutical products are sold to customers through arrangements with group purchasing organizations, or GPOs, and distributors. The majority of hospitals contract with the GPO of their choice for their purchasing needs. We currently derive, and expect to continue to derive, a large percentage of our revenue from customers that are members of a small number of GPOs. Currently, fewer than ten GPOs control a large majority of sales to hospital customers. We have purchasing arrangements with the major GPOs in the United States, including AmeriNet, Inc., Broadlane Healthcare Corporation, Consorta, Inc., MedAssets Inc., Novation, LLC, Owen Healthcare, Inc., PACT, LLC, Premier Purchasing Partners, LP, International Oncology Network, or ION, National Oncology Alliance, or NOA, and U.S. Oncology, Inc. In order to maintain these relationships, we believe we need to be a reliable supplier, offer a broad product line, remain price competitive, comply with FDA regulations and provide high-quality products. The GPOs through which we sell our products also have purchasing agreements with other manufacturers that sell competing products and the bid process for products such as ours is highly competitive. Most of our GPO agreements may be terminated on short notice. If we are unable to maintain our arrangements with GPOs and key customers, sales of our products and revenue would decline.

### **Our strategy to license rights to or acquire and commercialize proprietary, biological injectable or other specialty injectable products may not be successful, and we may never receive any return on our investment in these product candidates.**

Because our research and development activities are not focused on the development of proprietary products, we have and intend to license rights to or acquire products from third parties. Additionally, we are in

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the process of establishing our capabilities in biologic generic products so that we are able to offer such products when regulatory approvals and patents allow for such products. Other companies, including those with substantially greater financial and sales and marketing resources, will compete with us to license rights to or acquire these products. We may not be able to license rights to or acquire these proprietary, or other, products on acceptable terms, if at all. Even if we obtain rights to a pharmaceutical product and commit to payment terms, including, in some cases, significant up-front license payments, we may not be able to generate product sales sufficient to create a profit or otherwise avoid a loss.

A product candidate may fail to result in a commercially successful drug for other reasons, including the possibility that the product candidate may:

- be found during clinical trials to be unsafe or ineffective
- fail to receive necessary regulatory approvals
- be difficult or uneconomical to produce in commercial quantities
- be precluded from commercialization by proprietary rights of third parties
- fail to achieve market acceptance

Our marketing strategy, distribution channels and levels of competition with respect to any licensed or acquired product may be different from those of our current products, and we may not be able to compete favorably in any new product category.

### **American BioScience owns a significant percentage of our common stock and could exercise significant influence over matters requiring stockholder approval, regardless of the wishes of other stockholders.**

American BioScience owns approximately 67.9% of our common stock and has the ability to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of significant corporate transactions such as mergers, consolidations and sales of assets. Our Executive Chairman, Dr. Soon-Shiong, is also the president, chief financial officer and a director of American BioScience. Dr. Soon-Shiong also beneficially owns over a majority of the outstanding capital stock of American BioScience. 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, which could cause the market price of our common stock to fall or prevent stockholders from receiving a premium in such a transaction. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

### **We have a potential conflict of interest with respect to American BioScience that we may not be able to resolve on terms favorable to us.**

Conflicts may arise between American BioScience and us in a number of areas relating to our past and ongoing relationships, including:

- intellectual property matters, as well as licensing arrangements we have entered, or may enter, into with American BioScience
- employee retention and recruiting
- loans
- payment of dividends
- issuances of capital stock
- election of directors
- business opportunities that may be attractive to both American BioScience and us

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In addition, our Executive Chairman, Patrick Soon-Shiong, M.D., is also the president, chief financial officer and a director of American BioScience and beneficially owns over 80% of the outstanding capital stock of American BioScience. As a result, he may experience conflicts of interest with respect to decisions involving business opportunities and similar matters that may arise in the ordinary course of our business or the business of American BioScience.

We expect to resolve potential conflicts of interest on a case-by-case basis, in the manner required by applicable law and customary business practices. We entered into an agreement with American BioScience in July 2001 under which we acknowledged and agreed that Dr. Soon-Shiong may devote time to the business of, receive remuneration from and present business opportunities to American BioScience and that American BioScience's business and operations may compete with us. This agreement also requires that certain corporate opportunities that may become known to Dr. Soon-Shiong be presented to either us or American BioScience depending upon the clinical status of the corporate opportunity. Generally, any corporate opportunity in late stage clinical development would be first available to us. This agreement does not ensure the continued services of Dr. Soon-Shiong. Resolutions of some potential conflicts of interest are subject to review and approval by our Board of Directors, and require, in some instances, approval by a majority of the independent and disinterested non-executive directors. We still may be unable, however, to resolve some potential conflicts of interest with American BioScience and Dr. Soon-Shiong and, even if we do, the resolution may be less favorable than if we were dealing with an unaffiliated party because of their controlling interest in our company. Nothing restricts American BioScience from competing with us, and American BioScience is not obligated to engage in any future business transactions with us or license any products it may develop in the future to us.

### **We depend heavily on the principal members of our management and research and development teams, the loss of whom could harm our business.**

We depend heavily on the principal members of our management and research and development teams, including Dr. Patrick Soon-Shiong, our Executive Chairman, Alan Heller, our President and Chief Executive Officer, Tony Pera, Executive Vice President of the Generic Business and Nicole Williams, our Executive Vice President and Chief Financial Officer. Each of the members of our executive management team is employed "at will". With the exception of Mr. Heller, we do not have employment agreements with any of these individuals. The loss of the services of any one of our executive management team may significantly delay or prevent the achievement of our product development or business objectives.

### **We depend on third parties to supply raw materials and other components and may not be able to obtain sufficient quantities of these materials, which will limit our ability to manufacture our products on a timely basis and harm our operating results.**

The manufacture of our products requires raw materials and other components that must meet stringent FDA requirements. Some of these raw materials and other components are available only from a limited number of sources. Additionally, our regulatory approvals for each particular product denote the raw materials and components, and the suppliers for such materials, we may use for that product. Obtaining approval to change, substitute or add a raw material or component, or the supplier of a raw material or component, can be time consuming and expensive, as testing and regulatory approval is necessary. In the past, we have experienced shortages in some of the raw materials and components we purchase. If our suppliers are unable to deliver sufficient quantities of these materials on a timely basis or we encounter difficulties in our relationships with these suppliers, the manufacture and sale of our products may be disrupted, and our business, operating results and reputation could be adversely affected.

### **Other companies may claim that we infringe their intellectual property or proprietary rights, which could cause us to incur significant expenses or prevent us from selling our products.**

Our success depends in part on our ability to operate without infringing the patents and proprietary rights of third parties. The manufacture, use and sale of new products with conflicting patent rights have been subject to

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substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. Infringement litigation is prevalent with respect to generic versions of products for which the patent covering the brand name product is expiring, particularly since many companies which market generic products focus their development efforts on products with expiring patents. A number of pharmaceutical companies, biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover aspects of our products or our licensors' products, product candidates or other technologies.

Future or existing patents issued to third parties may contain claims that conflict with our products. We are subject to infringement claims from time to time in the ordinary course of our business, and third parties could assert infringement claims against us in the future with respect to our current products, products we may develop or products we may license. Litigation or interference proceedings could force us to:

- stop or delay selling, manufacturing or using products that incorporate or are made using the challenged intellectual property
- pay damages
- enter into licensing or royalty agreements that may not be available on acceptable terms, if at all

Any litigation or interference proceedings, regardless of their outcome, would likely delay the regulatory approval process, be costly and require significant time and attention of key management and technical personnel.

### **Our inability to protect our intellectual property rights in the United States and foreign countries could limit our ability to manufacture or sell our products.**

We rely on trade secrets, unpatented proprietary know-how, continuing technological innovation and, in some cases, patent protection to preserve our competitive position. Our patents and those for which we have or will license rights, including for ABRAXANE™, may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. Third party patents could reduce the coverage of the patents license, or that may be license to or owned by us. If patents containing competitive or conflicting claims are issued to third parties, we may be prevented from commercializing the products covered by such patents, or may be required to obtain or develop alternate technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies.

We may not be able to prevent third parties from infringing or using our intellectual property. We generally control and limit access to, and the distribution of, our product documentation and other proprietary information. Despite our efforts to protect this proprietary information, however, unauthorized parties may obtain and use information that we regard as proprietary. Other parties may independently develop similar know-how or may even obtain access to our technologies.

The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries.

The U.S. Patent and Trademark Office and the courts have not established a consistent policy regarding the breadth of claims allowed in pharmaceutical patents. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights.

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### **We may need to change our business practices to comply with changes to, or may be subject to charges under, the fraud and abuse laws.**

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback, marketing and pricing laws. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs such as Medicare and Medicaid. We may have to change our business practices, or our existing business practices could be challenged as unlawful due to changes in laws, regulations or rules or due to administrative or judicial findings, which could materially adversely affect our business.

### **We may become subject to federal false claims or other similar litigation brought by private individuals and the government.**

The Federal False Claims Act allows persons meeting specified requirements to bring suit alleging false or fraudulent Medicare or Medicaid claims and to share in any amounts paid to the government in fines or settlement. These suits, known as qui tam actions, have increased significantly in recent years and have increased the risk that a health care company will have to defend a false claim action, pay fines and/or be excluded from Medicare and Medicaid programs. Federal false claims litigation can lead to civil monetary penalties, criminal fines and imprisonment and/or exclusion from participation in Medicare, Medicaid and other federally funded health programs. Other alternate theories of liability may also be available to private parties seeking redress for such claims. A number of parties have brought claims against numerous pharmaceutical manufacturers, and we cannot be certain that such claims will not be brought against us, or if they are brought, that such claims might not be successful.

### **Our stock price has been volatile in response to market and other factors.**

The market price for our common stock has been and may continue to be volatile and subject to price and volume fluctuations in response to market and other factors, including the following, some of which are beyond our control:

- variations in our quarterly operating results from the expectations of securities analysts or investors;
- revisions in securities analysts' estimates;
- announcements of technological innovations or new products or services by us or our competitors;
- announcements by us or our competitors of significant acquisition, strategic partnerships, joint ventures or capital commitments;
- general technological, market or economic trends.
- investor perception of our industry or our prospects;
- insider selling or buying;
- investors entering into short sale contracts;
- regulatory developments affecting our industry; and
- additions or departures of key personnel.

### **Item 2. *Properties***

We operate various facilities in the United States, Canada and Switzerland, which have an aggregate size of approximately 749,000 square feet.

Our principal executive offices are located in Schaumburg, Illinois and occupy a total of 45,400 square feet of space under a lease that expires in May 2016. Additionally, we occupy 20,700 of leased space in Schaumburg under a lease that expires in June 2005 which is used for technology and training activities. We also lease a sales

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and administrative office in Los Angeles, California that occupies 5,300 square feet under a lease that expires in March 2007. Our business office in Ontario, Canada consists of 10,100 square feet of office space under a lease that expires in June 2014. In Bensenville, Illinois, we operate a distribution facility of approximately 100,000 square feet under a lease that expires in September 2007. In December 2004, we entered into an 18 month lease for 23,000 square feet of space in Rosemont, Illinois to be used as transitional space during our refurbishment of the Melrose Park research facility.

We own and operate manufacturing facilities of approximately 122,000 square feet and 160,000 square feet of manufacturing, packaging, laboratory, office and warehouse space in Melrose Park, Illinois and Grand Island, New York, respectively. We own and operate a research and development facility of approximately 140,000 square feet in Melrose Park, Illinois. In 2003, we acquired a additional facility in Grand Island, New York which encompasses approximately 120,000 square feet, on over 20 acres, and will be used to expand certain of our warehousing and manufacturing operations. In 2004, we acquired a manufacturing facility of approximately 25,000 square feet in Barbengo, Switzerland.

### **Item 3. Legal Proceedings**

In October and November of 2003, several purported federal securities class action lawsuits were filed against us in the United States District Court for the Northern District of Illinois. All of the class action lawsuits were consolidated in March 2004. In February 2005, the consolidated federal class action lawsuit against us was voluntarily dismissed by the plaintiffs with prejudice.

Additionally, in December 2003 a purported shareholder derivative action was filed in the Circuit Court of Cook County, Illinois, Chancery Division against each member of our Board of Directors and one non-director executive officer alleging essentially the same claims as were alleged in the federal class action lawsuit. In March 2005, the shareholder derivative action was voluntarily dismissed by the plaintiffs without prejudice.

We are from time to time subject to claims and litigation arising in ordinary courses of business. These claims have included assertions that our products infringe existing patents and also claims that the use of our products has caused personal injuries. We intend to defend vigorously any such litigation that may arise under all defenses that would be available to us. In the opinion of management, the ultimate outcome of proceedings of which management is aware, even if adverse to us, will not have a material adverse effect on our consolidated financial position or results of operations.

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

At the 2004 Annual Meeting of Stockholders held on December 13, 2004, our stockholders elected six persons to our Board of Directors and ratified and approved the appointment of Ernst & Young LLP as our independent auditors for the year ending December 31, 2004.

In connection with the election of directors, the shares of common stock present in person or by proxy were voted as follows:

	<u>For</u>	<u>Withheld</u>
Patrick Soon-Shiong, M.D.	66,673,388	1,552,276
Derek J. Brown	18,687,083	49,538,581
David S. Chen, Ph.D.	67,984,789	240,875
Stephen D. Nimer, M.D.	67,989,685	235,979
Leonard Shapiro	67,980,109	245,555
Kirk K. Calhoun	66,659,708	1,565,956

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All of the directors elected at the 2004 Annual Meeting of Stockholders were incumbent directors whose term of office continued after the meeting. Following the 2004 Annual Meeting of Stockholders, our Board of Directors elected Alan Heller to serve as a director to fill the vacancy on the board.

In connection with the proposal to approve the ratification and approval of the appointment of Ernst & Young LLP as our independent auditors for the year ending December 31, 2004: 68,033,950 shares were voted in favor of the proposal, 163,458 shares were voted against the proposal, and holders of 28,256 shares abstained.

There were no broker non-votes with respect to either of the above matters.

**PART II****Item 5. Market For Registrant's Common Equity and Related Stockholder Matters****Market for Common Stock**

Our common stock is listed and traded on the NASDAQ National Market under the symbol "APPX." The following table sets forth the high and low split-adjusted prices for our common stock as reported by NASDAQ for fiscal year 2004 and for 2003:

	2004 Price Per Share		2003 Price Per Share	
	High	Low	High	Low
For the quarter ended:				
March 31,	\$43.25	\$32.73	\$18.50	\$11.48
June 30,	\$49.19	\$30.20	\$26.42	\$10.55
September 30,	\$33.23	\$24.38	\$44.15	\$22.33
December 31,	\$40.62	\$21.28	\$39.30	\$22.65

As of March 8, 2005, the closing price for our common stock, as reported on NASDAQ, was \$50.00 per share. On March 8, 2005, we had approximately 85 holders of record of our common stock.

**Dividend Policy**

No cash dividends were declared or paid in fiscal 2004, fiscal 2003 or fiscal 2002. We have no current intention of paying cash dividends.

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**Item 6. Selected Financial Data**

	Year Ended December 31,				
	2004	2003	2002	2001	2000
(in thousands, except per share data)					
<b>CONSOLIDATED STATEMENT OF OPERATIONS DATA:</b>					
Net sales	\$405,010	\$351,315	\$277,474	\$192,029	\$165,495
Cost of sales	189,301	159,938	140,512	121,619	105,587
Gross profit	215,709	191,377	136,962	70,410	59,908
Operating expenses:					
Research and development (exclusive of stock-based compensation)	25,797	22,507	14,474	13,790	13,016
Selling, general and administrative (exclusive of stock-based compensation)	92,034	52,719	44,285	30,911	30,048
Milestone payment	10,000	—	—	—	—
Stock-based compensation (1)	1,077	1,215	2,347	2,491	615
(Gain) loss on litigation settlements, net	—	—	—	(750)	28,353
Equity in net (income) loss of Drug Source Co., LLC	(2,084)	(1,837)	(1,666)	(1,414)	122
Total operating expenses	126,824	74,604	59,440	45,028	72,154
Operating income (loss)	88,885	116,773	77,522	25,382	(12,246)
Interest income	1,790	1,758	2,135	1,204	200
Interest and other income (expense)	144	537	(1,358)	(4,419)	(1,751)
Loss on early extinguishment of credit facility	(1,986)	—	—	—	—
Income (loss) before income taxes	88,833	119,068	78,299	22,167	(13,797)
Provision (benefit) for income taxes	32,140	47,375	33,100	9,539	(5,038)
Net income (loss)	56,693	71,693	45,199	12,628	(8,759)
Less imputed preferred stock dividends	—	—	—	(951)	(1,000)
Income (loss) applicable to common stock	\$ 56,693	\$ 71,693	\$ 45,199	\$ 11,677	\$ (9,759)
Income (loss) per common share (2):					
Basic	\$ 0.81	\$ 1.03	\$ 0.62	\$ 0.31	\$ (0.29)
Diluted	\$ 0.78	\$ 0.99	\$ 0.60	\$ 0.20	\$ (0.29)
Weighted-average common shares outstanding:					
Basic	70,305	69,673	72,711	37,077	33,792
Diluted	73,147	72,745	75,479	58,422	33,792
<b>OTHER DATA:</b>					
Cash flow provided by operating activities	\$ 47,231	\$ 57,525	\$ 37,863	\$ 11,605	\$ 18,580
Purchases of property, plant and equipment, product license rights and other	(41,481)	(24,432)	(19,166)	(9,146)	(11,851)
Cash flow provided by (used in) financing activities	3,723	(14,390)	75,610	93,722	(11,661)
<b>CONSOLIDATED BALANCE SHEET DATA:</b>					
Working capital	\$195,629	\$160,019	\$107,825	\$ 76,421	\$ 25,249
Total assets	373,333	303,785	220,976	239,787	122,823
Long-term debt, including current portion	—	—	—	—	18,939
Series A redeemable convertible preferred stock	—	—	—	—	12,583
Total stockholders' equity	312,691	246,061	180,708	130,070	38,699

(1) We recorded stock-based compensation related to certain stock option grants. Stock-based compensation relates to the following:

	Year Ended December 31,				
	2004	2003	2002	2001	2000
(in thousands)					
Research and development	\$ 41	\$ 70	\$ 195	\$ 182	\$ 73
Selling, general and administrative	1,036	1,145	2,152	2,309	542
	\$1,077	\$1,215	\$2,347	\$2,491	\$615

(2) See Note 2 to our consolidated financial statements for an explanation of the number of shares used to compute basic and diluted net income (loss) per common share.

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

#### **Note Regarding Forward-Looking Statements**

*You should read this discussion together with our consolidated financial statements and accompanying notes included in this Annual Report on Form 10-K.*

Statements contained in this Annual Report on Form 10-K, which are not historical facts, are forward-looking statements, as the term is defined in the Private Securities Litigation Reform Act of 1995. Such forward-looking statements, whether expressed or implied, are subject to risks and uncertainties which can cause actual results to differ materially from those currently anticipated, due to a number of factors, which include, but are not limited to:

- the market adoption of and demand for our existing and new pharmaceutical products, including ABRAXANE™;
- the amount and timing of costs associated with the continuing launch of ABRAXANE™;
- the actual results achieved in further clinical trials of ABRAXANE™ may or may not be consistent with the results achieved to date;
- the impact of competitive products and pricing;
- the ability to successfully manufacture products in an efficient, time-sensitive and cost effective manner;
- the impact on our products and revenues of patents and other proprietary rights licensed or owned by us, our competitors and other third parties;
- our ability, and that of our suppliers, to comply with laws, regulations, and standards, and the application and interpretation of those laws, regulations, and standards, that govern or affect the pharmaceutical industry, the non-compliance with which may delay or prevent the sale of our products;
- the difficulty in predicting the timing or outcome of product development efforts and regulatory approvals;
- the ability to successfully integrate the recent and potential future acquisitions;
- the availability and price of acceptable raw materials and component from third-party suppliers;
- evolution of the fee-for-service arrangements being adopted by our major wholesale customers;
- inventory reductions or fluctuations in buying patterns by wholesalers or distributors;
- the impact of recent legislative changes to the governmental reimbursement system.

Forward-looking statements also include the assumptions underlying or relating to any of the foregoing or other such statements. When used in this report, the words "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "continue," and similar expressions are generally intended to identify forward-looking statements.

Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's opinions only as of the date hereof. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements. Readers should carefully review the factors described in *Business: Factors that May Affect Future Results of Operations* and other documents we file from time to time with the Securities and Exchange Commission, including the Quarterly Reports on Form 10-Q to be filed by us in fiscal year 2005.

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### OVERVIEW

The overview section of Management's Discussion and Analysis of Financial Conditions and Results of Operations, or MD&A, is designed to provide the reader with summary level information on: our history, strategy, highlights of our 2004 results and our outlook for 2005. Following this overview the MD&A is organized as follows:

- a discussion of our operating results,
- a review of factors impacting our liquidity and cash flow,
- a discussion of accounting policies and estimates critical to an understanding of the assumptions and judgments incorporated in our financial results,
- information on the license and manufacturing agreements underlying our proprietary oncology product, ABRAXANE™,
- a summary of our contractual obligations, and
- our assessment of the potential impact of recent accounting pronouncements on the Company.

The MD&A should be read in conjunction with the other sections of this Annual Report on Form 10-K, including "Item 1: Business"; "Item 6: Selected Financial Data"; and "Item 8: Financial Statements and Supplemental Data."

### Background

We are a pharmaceutical company that develops, manufactures and markets injectable pharmaceutical products. We believe that we are the only independent U.S. public company with a primary focus on the injectable oncology, anti-infective and critical care markets, and we further believe that we offer one of the most comprehensive injectable product portfolios in the pharmaceutical industry. We manufacture products in each of the three basic forms in which injectable products are sold: liquid, powder and lyophilized, or freeze-dried.

Our products are generally used in hospitals, long-term care facilities, alternate care sites and clinics within North America. Unlike the retail pharmacy market for oral products, the injectable pharmaceuticals marketplace is largely made up of end users who have relationships with group purchasing organizations, or GPOs, and/or specialty distributors who distribute products within a particular end-user market, such as oncology clinics. GPOs and specialty distributors generally enter into collective product purchasing agreements with pharmaceutical suppliers in an effort to secure more favorable drug pricing on behalf of their members.

We began in 1996 with an initial focus on U.S. marketing and distribution of generic pharmaceutical products manufactured by others. In June 1998, we acquired Fujisawa USA, Inc.'s generic injectable pharmaceutical business including manufacturing facilities in Melrose Park, Illinois and Grand Island, New York and our research and development facility in Melrose Park, Illinois. We also acquired additional assets in this transaction, including inventories, plant and equipment and abbreviated new drug applications that were approved by or pending with the U.S. Food and Drug Administration, or FDA.

We hold the exclusive North American right to sell ABRAXANE™, a proprietary nanoparticle injectable oncology product that is a patented formulation of paclitaxel. Paclitaxel is the active ingredient in Taxol®, one of the world's top selling cancer drugs. In January 2005, we announced that American BioScience's New Drug Application, or NDA, for ABRAXANE™ had been approved by the U.S. Food and Drug Administration, or FDA, and we launched the product on February 7, 2005. ABRAXANE™, consists only of albumin-bound paclitaxel nanoparticles, is free of toxic solvents and demonstrated a superior response rate with an almost doubling of the reconciled target lesion response rate when compared with the solvent-based Taxol® in a prospectively randomized trial of 460 patients with metastatic breast cancer. Because it contains no toxic solvents, this next-generation taxane product enables the administration of 50% more chemotherapy with a well-tolerated safety profile, requires no routine premedication to prevent hypersensitivity reactions and can be given over a shorter infusion time using standard IV tubing.

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We are a Delaware corporation that was formed in 2001 as successor to a California corporation formed in 1996. We are a majority owned subsidiary of American BioScience, Inc., a California corporation. At December 31, 2004, American BioScience owned 47,984,160 shares, or 67.9%, of our outstanding common stock.

### **Strategy**

Our goal is to expand upon our position as an industry leader in the development, manufacture, sale and distribution of injectable pharmaceutical products, with an intent on offering a broad portfolio of injectable products affecting every aspect of hospital care. Key elements of our strategy include:

- quickly develop the market for our new proprietary oncology product, ABRAXANE™, via strong marketing and educational programs, introduction into other licensed North American markets and further clinical pursuit of the use of ABRAXANE™ in other indications and treatment regimens;
- continued focus on other new, higher-margin injectable product opportunities, including: complementary proprietary products; generic opportunities as products approach patent expiry; low molecular weight heparins; and, as the FDA regulatory environment evolves, generic biological products;
- maintaining and improving our current Good Manufacturing Practice, or cGMP, product development and manufacturing capabilities and creating capacity to meet future market needs and evolving regulatory requirements;
- making targeted acquisitions to enhance our product offerings, market presence and capabilities, both in the United States and globally;
- advancing our strategic sourcing capabilities to obtain raw materials, intellectual property, technology and processes necessary to develop and manufacture both future and existing products.

### **Highlights**

- The FDA approved our licensed oncology product candidate, ABRAXANE™, for the filed indication on January 7, 2005. ABRAXANE™ was launched on February 7, 2005 and the first commercial patient treated on February 9. ABRAXANE™, consists only of albumin-bound paclitaxel nanoparticles, is free of toxic solvents and demonstrated a superior response rate with an almost doubling of the reconciled target lesion response rate when compared with the solvent-based Taxol® in a prospectively randomized trial of 460 patients with metastatic breast cancer. In the overall patient population, median survival for those patients receiving ABRAXANE was 10 weeks longer (65.0 weeks v. 55.7 weeks) than for patients receiving Taxol but this difference did not reach statistical significance. However there was a significant prolongation in survival (p=0.016) in patients receiving ABRAXANE in the second-line or greater setting as compared to those receiving Taxol (56.4 weeks vs. 46.7 weeks). In this group, there was a 29% reduction in the risk of death (i.e., hazard ratio of 0.71) for patients who received ABRAXANE compared to those who received Taxol.

Because it contains no toxic solvents, this next-generation taxane product enables the administration of 50% more chemotherapy with a well-tolerated safety profile, requires no routine premedication to prevent hypersensitivity reactions and can be given over a shorter infusion time using standard IV tubing. American BioScience has also conducted a Phase II clinical trial to explore a weekly dosing regimen of ABRAXANE™ in metastatic breast cancer patients in which prior taxane therapy failed and Phase I and/or Phase II trials evaluating ABRAXANE™ in non-small cell lung, head and neck, ovarian, melanoma and cervical cancers, the rights to which we have licensed. To date, approximately 40 ABRAXANE™ clinical trials have been initiated or are planned in various settings, including those listed above, and prostate cancer.

- Financially, 2004 ended on a strong note as, in the fourth quarter, we achieved record quarterly net sales of \$122.6 million, up 37% over the prior year fourth quarter, and record net income of \$21.9 million, or \$0.30 per diluted share, inclusive of \$9.4 million, or \$0.08 per share of ABRAXANE expense. For all of fiscal 2004, net sales increased 15% to \$405.0 million, we achieved gross margin of 53.3% and net

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income, including \$49.8 million, or \$0.42 per diluted share, of ABRAXANE™ related expenses, was \$56.7 million, or \$0.78 per diluted share. We generated operating cash flow of \$47.2 million in 2004, after funding \$49.8 million in ABRAXANE™ expense and the acquisition of approximately \$22 million in ABRAXANE™ raw inventory. Additionally, our equity base increased by 27%, or \$66.6 million, in 2004.

- We achieved 15 FDA approvals in 2004, including 14 Abbreviated New Drug Application, or ANDA, approvals, one final approval for a product for which we had already received a tentative approval, and our first New Drug Application, or NDA, approval, Tobramycin Powder. We currently have 20 ANDAs on file and under review at the FDA and over 50 additional products under development. The following table highlights recent approvals.

### Summary of 2004 Approvals, Approved Filings and Launch Activity

Product	Brand Name	Indication	Approval Date	Launch Date
Amiodarone Hydrochloride	Cordarone I.V.®	Critical Care	10/27/04	Nov-04
Carboplatin (Liquid)	Paraplatin®	Oncology	10/18/04	Oct-04
Carboplatin (Lyophilized)	Paraplatin®	Oncology	5/22/02	Oct-04
Flumazenil	Romazicon®	Critical Care	10/13/04	Oct-04
Methylprednisolone Sodium	Solu-Medrol®	Critical Care	8/2/04	Aug-04
Esmolol Hydrochloride (t)	Brevibloc®	Critical Care	7/21/04	2005 (e)
Dimenhydrinate	Dramamine®	Critical Care	6/24/04	Aug-04
Tobramycin (NDA)	Nebcin®	Anti-Infective	7/15/04	Aug-04
Terbutaline Sulfate	Brethine®	Critical Care	5/28/04	Jun-04
Cladribine	Leustatin®	Oncology	5/27/04	Sep-04
Ciprofloxacin (t)	Cipro®	Anti-Infective	2/19/04	2006 (e)
Cytarabine	Cytosar-U®	Oncology	1/15/04	Mar-04
Piperacillin	Pipracil®	Anti-Infective	11/14/03	Jan-04
Fluconazole	Diflucan®	Critical Care	4/15/03	TBD
Vincristine	Oncovin®	Oncology	12/20/02	TBD
Bacitracin	Bacitracin®	Anti-Infective	1/3/02	Jun-04

(t) – tentative FDA approval, as of the date of this filing, pending only patent expiry and any subsequent exclusivity periods.

(e) – expected, actual launch could be delayed.

- On July 28, 2004, we acquired certain assets, including a 25,000 square foot manufacturing facility and certain injectable oncology product rights for a purchase price of approximately \$11 million in cash, subject to final adjustment. Located in Barbengo, Switzerland, the FDA approved facility uses Isolator Technology which is particularly suitable for the manufacture of oncolytic products, including daunorubicin, methotrexate, and leucovorin calcium, for our U.S. operations. Additionally, we acquired eight FDA approved ANDAs covering 15 product codes and one ANDA pending with the U.S. FDA in the transaction which also included a number of generic injectable oncology products currently marketed in Europe and South America and a number of Marketing Authorization Applications, or MAAs, currently approved or pending with the European Agency for the Evaluation of Medicinal Products.

### 2005 Outlook

American Pharmaceutical Partners' expectations for 2005 follow:

- net sales in the core generic injectable business are expected to grow in the mid-teens as compared to 2004;
- our 2005 net sales estimate for ABRAXANE™ is based, in part, on market data, consumer studies and other research and is subject to the inherent difficulty in predicting demand for new products which require estimates as to end-user demand, the rate and timing of market penetration, competition and

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other market and reimbursement issues. Given these parameters, net sales for ABRAXANE™ are anticipated to be in the range of \$125 million to \$155 million in 2005;

- 2005 gross margin percentage, after any ABRAXANE™ profit sharing, is anticipated to be in the high 50 percent range relative to net sales;
- expenses related to ABRAXANE™ are expected to be approximately \$40 million for the first six months of 2005, primarily reflecting significant ongoing launch activities and the expansion of manufacturing capabilities; and
- operating expenses related to core business and corporate activities are anticipated to increase in line with the 2005 core sales increase.

## RESULTS OF OPERATIONS

### Overview

The following table sets forth the results of our operations for each of the three years ended December 31, 2004, and forms the basis for the following discussion of our operating activities:

	Year Ended December 31,			Change Favorable (Unfavorable)			
	2004	2003	2002	2004 vs. 2003		2003 vs. 2002	
				\$	%	\$	%
(in thousands, except per share data and percentages)							
<b>Consolidated statement of income data:</b>							
Net sales							
Critical care	\$178,242	\$169,849	\$135,370	\$ 8,393	5%	\$ 34,479	25%
Anti-infective	125,052	95,581	74,082	29,471	31%	21,499	29%
Oncology	95,866	81,049	61,204	14,817	18%	19,845	32%
Contract manufacturing and other	5,850	4,836	6,818	1,014	21%	(1,982)	-29%
Total net sales	405,010	351,315	277,474	53,695	15%	73,841	27%
Cost of sales	189,301	159,938	140,512	(29,363)	-18%	(19,426)	-14%
Gross profit	215,709	191,377	136,962	24,332	13%	54,415	40%
	<i>Percent to net sales</i>	<i>53.3%</i>	<i>54.5%</i>				
Operating expenses:							
Research and development costs	25,797	22,507	14,474	(3,290)	-15%	(8,033)	-55%
	<i>Percent to net sales</i>	<i>6.4%</i>	<i>6.4%</i>				
Selling, general and administrative expenses	92,034	52,719	44,285	(39,315)	-75%	(8,434)	-19%
	<i>Percent to net sales</i>	<i>22.7%</i>	<i>15.0%</i>				
Milestone payment	10,000	—	—	(10,000)	—	—	—
Stock-based compensation	1,077	1,215	2,347	138	11%	1,132	48%
Equity in net income of Drug Source Co., LLC	(2,084)	(1,837)	(1,666)	247	13%	171	10%
Total operating expenses	126,824	74,604	59,440	(52,220)	-70%	(15,164)	-26%
	<i>Percent to net sales</i>	<i>31.3%</i>	<i>21.2%</i>				
Operating income	88,885	116,773	77,522	(27,888)	-24%	39,251	51%
	<i>Percent to net sales</i>	<i>21.9%</i>	<i>33.2%</i>				
Interest income	1,790	1,758	2,135	32	2%	(377)	-18%
Interest and other (expense) income	144	537	(1,358)	(393)	73%	1,895	140%
Loss on early extinguishment of credit facility	(1,986)	—	—	(1,986)	—	—	—
Income before income taxes	88,833	119,068	78,299	(30,235)	-25%	40,769	52%
Provision for income taxes	32,140	47,375	33,100	15,235	32%	(14,275)	-43%
Net income	\$ 56,693	\$ 71,693	\$ 45,199	\$(15,000)	-21%	\$ 26,494	59%
	<i>Percent to net sales</i>	<i>14.0%</i>	<i>20.4%</i>				
Income per common share:							
Basic	\$ 0.81	\$ 1.03	\$ 0.62				
Diluted	\$ 0.78	\$ 0.99	\$ 0.60				
Weighted-average common shares outstanding:							
Basic	70,305	69,673	72,711				
Diluted	73,147	72,745	75,479				

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### Operating Results

#### *Net Sales*

Net 2004 sales increased \$53.7 million, or 15%, to \$405.0 million. Anti-infective net sales increased \$29.5 million, or 31%, in 2004 driven by \$10.0 million in sales of recently launched antibiotics, including bacitracin, tobramycin and piperacillin, and good demand, including market opportunities, and stable pricing for our more mature antibiotic products. Oncolytic net sales increased \$14.8 million, or 18%, in 2004 primarily due to the October 2004 launch of carboplatin and increased penetration into the specialty oncology distribution channel by pamidronate and other key oncology products, partially offset by anticipated, ongoing price erosion on maturing oncolytic products. Critical care net sales increased \$8.4 million, or 5%, in 2004 due primarily to new products, including terbutaline and methylprednisolone and increased unit volume for other key critical care products.

Net sales in 2003 increased \$73.8 million, or 27%, due primarily to products launched during 2002, favorable pricing and strong demand for more mature products and increased market penetration for certain key products.

#### *Gross Profit*

During 2004, gross profit increased \$24.3 million, or 13%, on a 15% increase in net sales. Gross profit as a percentage of net sales was 53.3% and 54.5% in 2004 and 2003, respectively. The decrease in 2004 gross profit as a percentage of net sales was primarily due to the 2004 impact of price declines, principally in late 2003 on products launched in 2002, and the cost and sales impact of an extended seasonal plant shutdown in the 2004 first quarter, partially offset by the introduction of new, higher margin, products in late 2004. Typically, newly approved and marketed generic injectable products yield significantly higher gross margins relative to sales than do mature products, with gross margin on such products generally expected to decline over time due to competitive factors in the market place.

Gross profit in 2003 increased \$54.4 million, or 40%, on a 27% sales increase, representing 54.5% of sales in 2003 as compared to 49.4% of sales in 2002. The increase in 2003 gross profit as a percentage of net sales was primarily due to the contribution of products launched in 2002, favorable market conditions for generic injectables, higher margin market opportunities for certain existing products and first-half efficiencies resulting from higher unit production volumes. Gross profit margins declined slightly as the year progressed due primarily to anticipated, albeit later than expected, price declines on certain more recently launched products.

#### *Research and development, or R&D*

R&D expense increased by \$3.3 million, or 15%, in 2004 due principally to a \$3.0 million increase in ABRAXANE™ pre-production costs, and increased development activity, and the timing of such activity, on the generic side of the business.

R&D expense in 2003 increased by \$8.0 million, or 55%, due to pre-production work on products in late-stage development, including \$4.9 million of ABRAXANE™ production development costs, and to the increased cost of raw materials used in other development activities.

#### *Selling, general and administrative, or SG&A*

SG&A expense increased \$39.3 million, or 75%, due to a \$27.4 million increase in ABRAXANE™ sales and marketing pre-launch costs, increased staffing and related costs associated with growth in the core business, expense related to the Swiss facility acquired in July 2004, and expenses related to the implementation of an enterprise reporting system and the requirements of the Sarbanes-Oxley act. SG&A for the core injectable business, which excludes ABRAXANE™ pre-launch costs, was 14.9% of sales in 2004 as compared to 13.7% of sales in 2003 and 16.0% in 2002.

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SG&A expense in 2003 increased \$8.4 million, or 19%, due to \$4.4 million in sales and marketing start-up costs in anticipation of approval and launch of ABRAXANE<sup>TM</sup>, increased staffing requirements resulting from rapid sales growth, increased technology infrastructure and higher risk management costs.

### *Other Expenses*

In the second quarter of 2004, we expensed and paid a \$10.0 million milestone payment to American BioScience triggered by the FDA's May 8, 2004 acceptance of the ABRAXANE<sup>TM</sup> NDA filing.

Stock-based compensation expense declined \$0.1 million in 2004 as compared to the prior year due primarily to the accelerated amortization schedule used to expense such costs, largely offset by additional performance grants and a higher closing stock price. Stock-based compensation expense results from the issuance of stock based compensation which was either performance-based or, prior to the date of our initial public offering, for which the exercise price was less than the estimated fair value of common stock on the grant date.

Drug Source Company, LLC, a 50% owned company, acts as a selling agent of raw material to the pharmaceutical industry, including us. Our investment in Drug Source Company is intended to both generate a return on our investment and to strengthen our strategic sourcing capabilities over time. Because our 50% ownership interest in Drug Source Company does not provide financial or operational control of Drug Source Company, we account for our interest in Drug Source Company under the equity method. Equity income in Drug Source Company increased \$0.2 million, or 13%, in 2004 due primarily to the introduction of new products. Research and development expense included purchases from Drug Source Company of \$0.4 million and \$1.8 million in 2004 and 2003, respectively. Ending inventory included purchases from Drug Source Company of \$2.9 million and \$0.8 million at December 31, 2004 and 2003, respectively.

Interest income consists primarily of interest earned on the intercompany note from American BioScience and interest earned on invested cash, and was comparable between 2004 and 2003.

Interest expense and other consists primarily of miscellaneous interest expense and other financing costs. The credits in both 2004 and 2003 resulted primarily from foreign exchange gains on our intercompany trading account with Pharmaceutical Partners of Canada, our wholly owned subsidiary, as a result of the weaker U.S. dollar.

In the third quarter of 2004, we recorded a non-cash pretax charge of \$2.0 million to write-off unamortized debt acquisition costs related to the early extinguishment of our prior five-year credit facility.

### *Provision for income taxes*

Our 2004 provision for income taxes included the benefit of a \$1.7 million state investment tax credit finalized in the second quarter. Absent this benefit, our effective income tax rate in 2004 was 38.1% as compared to 39.8% and 42.3% in 2003 and 2002, respectively. The lower 2004 and 2003 effective tax rates on this comparable basis resulted primarily from a lower effective state income tax rate, favorable experience as a standalone tax entity and resolution of tax matters.

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[Table of Contents](#)**LIQUIDITY AND CAPITAL RESOURCES****Overview**

The following table summarizes key elements of our financial position and sources and (uses) of cash and cash equivalents for the three years ended December 31, 2004:

	Year Ended December 31,		
	2004	2003	2002
	(in thousands)		
<b>Summary Financial Position:</b>			
Cash, cash equivalents and short-term investments	\$ 67,629	\$ 58,625	\$ 39,771
Working capital	195,629	160,019	107,825
Total assets	373,333	303,785	220,976
Long-term debt, including current portion	—	—	—
Total stockholders' equity	312,691	246,061	180,708
<b>Summary of Sources and (Uses) of Cash and Cash Equivalents:</b>			
Operating activities	\$ 47,231	\$ 57,525	\$ 37,863
Purchases of property, plant and equipment, product license rights and other	(41,481)	(24,432)	(19,166)
Financing activities	3,723	(14,390)	(75,610)

We believe that our current cash and short-term investments, cash generated from operations, funds available from our revolving line of credit and the ability to issue debt or equity securities under our shelf registration will be sufficient to finance our operations, including ongoing launch activity relating to ABRAXANE<sup>™</sup>, product development and capital expenditures for at least the next 12 months. In the event we engage in future acquisitions we may have to raise additional capital through additional borrowings or the issuance of debt or equity securities pursuant to our shelf registration or otherwise.

*Capital Requirements*

Our capital requirements depend on numerous factors, including:

- working capital requirements and sales and marketing costs required to support our newly launched proprietary oncology product, ABRAXANE<sup>™</sup>;
- the need for manufacturing expansion and improvement;
- the requirements of our recent, and of any potential future, acquisitions, asset purchases or equity investments; and
- the amount of cash generated by operations.

We presently anticipate that our 2005 capital expenditure requirements will approximate \$60 million.

Adequate funds for these purposes may not be available when needed or on terms acceptable to us, and we may need to raise capital that may not be available on terms favorable or acceptable to us, if at all. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants. If we cannot raise money when needed, we may have to reduce or slow ABRAXANE<sup>™</sup> launch activities, reduce capital expenditures or scale back development of new products or other business activities.

*Sources of Financing*

In addition to available cash on hand, short-term investments and cash flow from operations, we have additional financing available under our unsecured, three-year \$100 million credit facility established in September 2004, which may be increased to \$150 million at our option. There were no balances outstanding under our credit facility and we were in compliance with all covenants at December 31, 2004.

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### Sources and Uses of Cash

#### *Operating Activities*

Cash flow from operations is our primary source of liquidity. Net cash provided by operating activities was \$47.2 million in 2004 as compared to \$57.5 million in 2003. The \$10.3 million decrease in 2004 cash provided by operating activities was due primarily to: a \$30.4 million increase in ABRAXANE™ sales, marketing and development expense; a \$10.0 million milestone payment triggered upon the FDA's May 2004 acceptance of the ABRAXANE™ NDA filing; and a \$40.7 million increase in inventory, all of which were substantially offset by strong cash flow in the core generic business.

The 2004 inventory increase was due to a \$22.3 million increase in ABRAXANE™ related inventory as the product approached launch, inventory supporting recently launched products and inventory necessary to support higher sales volumes. We had \$40.2 million and \$27.6 million of ABRAXANE™ related raw material inventory on hand at December 31, 2004 and 2003, respectively, and, at December 31, 2004, work-in-process inventory included \$7.7 million of finished ABRAXANE™ product pending only approval and final labeling.

Net cash provided by operating activities increased \$19.7 million in 2003 due primarily to a \$26.5 million increase in net income, after \$34.0 million in spending for ABRAXANE™ prelaunch raw material inventory and marketing expense.

#### *Investing Activities*

Our investing activities include capital expenditures necessary to expand and maintain our manufacturing capabilities and infrastructure and, to a lesser extent, outlays necessary to acquire various product or intellectual property rights. Also included in investing activities was \$13.3 million and \$53.2 million in 2004 and 2003, respectively, related to our purchase of short-term, highly-liquid, available-for-sale, municipal variable rate demand notes, which are recorded at cost, and may generally be redeemed upon seven days notice. Net cash used for the acquisition of property, plant and equipment and product license rights totaled \$41.5 million, \$24.4 million and \$19.2 million in 2004, 2003 and 2002, respectively. The 2004 increase resulted from the purchase of certain assets, including a manufacturing facility in Switzerland and certain injectable oncology rights in the 2004 second quarter for approximately \$11 million in cash, and a higher level of capital expenditures supporting additional or improved manufacturing capacity and information technology initiatives.

Net cash used for the acquisition of property, plant and equipment and product license rights in 2003 and 2002 consisted primarily of capital expenditures supporting manufacturing and information technology enhancement initiatives.

#### *Financing Activities*

Financing activities generally include the issuance or repurchase of our common stock, proceeds from the exercise of employee stock options and transactions with American BioScience, our parent company. Net cash provided by financing activities consisted primarily of \$4.7 million in cash proceeds from the exercise of employee stock options and sale of stock through the employee stock purchase program in 2004.

Net cash used in financing activities during 2003 was \$14.4 million, resulting primarily from the first quarter repurchase of 1,596,081 shares of our common stock on the open market for \$20.0 million. Cash used for share repurchases was partially offset by \$4.2 million in cash proceeds from the exercise of employee stock options and sale of stock to the employee stock purchase program during 2003.

The \$75.6 million net use of cash for financing in 2002 resulted from the initial \$60.0 million payment to American BioScience for ABRAXANE™ product license rights and the repurchase of \$36.3 million of common shares, partially offset by \$20.1 million in proceeds from the January 2002 over-allotment exercise. Due to its related party nature, the \$60.0 million license payment to our majority stockholder in 2002 has been presented as a financing activity on the cash flow statement, consistent with its treatment as a direct reduction in stockholders equity on our balance sheet.

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### Stock Repurchase Program

During the 2003 first quarter, we repurchased 1,596,081 of our shares in the open market for \$20.0 million. Additionally, in 2002, we repurchased all 4,371,891 shares of our common stock held by Premier Purchasing Partners LP, for \$30.3 million in cash, including transaction costs and repurchased 678,426 shares of our common stock owned by Biotechnology Development Fund, L.P. for \$6.0 million in cash. Share repurchases were funded using our internal cash resources and are being held as treasury shares to be used for general corporate purposes. In aggregate, the 6,646,398 common shares held as treasury stock at December 31, 2004 have a cost basis of \$8.47 per share.

### Contractual Obligations and Off-Balance Sheet Arrangements

The following information summarizes our contractual obligations and other commitments, consisting solely of operating leases, as of December 31, 2004:

	Total	Payments due by Period			
		Less than 1 year	1-3 years	3-5 years	After 5 years
		(in thousands)			
Operating leases	\$12,597	\$2,519	\$ 4,202	\$ 1,472	\$4,404

As of December 31, 2004, we did not have any off-balance sheet financing arrangements as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

### ABRAXANE™ LICENSE AND MANUFACTURING AGREEMENT

We hold the exclusive North American marketing rights and worldwide manufacturing rights for ABRAXANE™. The FDA approved ABRAXANE™, for the filed indication on January 7, 2005 and ABRAXANE™ was launched on February 7, 2005. ABRAXANE™ is licensed from American BioScience, which is responsible for conducting the clinical studies of and obtaining regulatory approval for ABRAXANE™.

In November 2001, we signed a perpetual license agreement with American BioScience under which we acquired the exclusive rights to market and sell ABRAXANE™ in North America for indications relating to breast, lung, ovarian, prostate and other cancers. Under the agreement, we made an initial payment to American BioScience of \$60.0 million and committed to future milestone payments contingent upon achievement of specified regulatory, publication and sales objectives for licensed indications. American BioScience is responsible for conducting clinical studies in support of ABRAXANE™ and for substantially all costs associated with the development and obtaining regulatory approval for ABRAXANE™, except that we provided \$2.0 million of ABRAXANE™ for use in clinical trials, the cost of which we charged to research and development expense in 2001. Any profit, as defined in the license agreement, resulting from our sales of ABRAXANE™ will be shared equally between American BioScience and us, following the recapture of half of the pre-launch sales, marketing and pre-production start-up costs we have incurred.

The terms of the license agreement were negotiated to reflect the value of the licensed product rights acquired, then in late-stage development, American BioScience's remaining obligation to complete the NDA filing and the potential sales of the product under licensed clinical indications. The license agreement was a product of several months of extensive negotiation with American BioScience involving outside counsel, investment banks and a nationally recognized valuation firm. Based upon the analysis and recommendations of our advisors, we believe that the overall terms of the agreement were fair to us, including in comparison to similar licenses between unrelated parties. The agreement was unanimously approved by the disinterested members of our Board of Directors, with those directors who also have an affiliation with American BioScience recusing themselves from the vote. There are no restrictions on how American BioScience would use payments made under the license agreement and we understand such payments have been and will be used both to fund the development of ABRAXANE™ in relation to our licensed product rights and for other purposes.

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In December 2001, in conjunction with our initial public offering, we recorded an initial payment due American BioScience of \$60.0 million. In our financial statements, the license agreement was accounted for as an asset contributed by a principal shareholder using the shareholder's historical cost basis, which was zero, and the \$60.0 million payment was accounted for as a distribution of stockholders' equity. For income tax purposes, the payment was recorded as an asset and is being amortized over a 15-year period. Because there was no corresponding charge to income, the income tax benefit of this payment is being credited to stockholders' equity as realized.

Under the license agreement, American BioScience earned milestone payments upon the filing and approval of ABRAXANE™ for the metastatic breast cancer indication. The first such milestone of \$10.0 million was achieved in May, 2004 when the FDA accepted American BioScience's NDA for the metastatic breast cancer indication. This payment was expensed and paid in the second quarter of 2004. The FDA then approved ABRAXANE™ for the filed indication in January 2005, triggering a \$15.0 million milestone payment in the first quarter of 2005, which will be capitalized and amortized over the expected life of the product, subject to periodic review for impairment.

Regulatory and publication achievements related to other licensed indications under study, including lung, ovarian and prostate cancers will trigger further milestone payments to American BioScience. Such payments generally total \$17.5 million per agreed indication. As with the indication of breast cancer, those payments earned prior to FDA approval for each indication will be expensed, while amounts earned upon FDA approval of those indications will be capitalized and amortized over the expected life of the product. We have the option not to make one or more of the milestone payments tied to certain indications under study if sales of the product do not meet specified levels.

Upon achievement of major annual one-time ABRAXANE™ sales milestones, we are required to make additional payments which, in the aggregate, could total \$110.0 million should annual ABRAXANE™ sales exceed \$1.0 billion. The first sales milestone payment of \$10.0 million would be triggered upon achievement of annual calendar year ABRAXANE™ sales in excess of \$200.0 million and the second sales milestone of \$20.0 million upon the achievement of annual calendar year sales in excess of \$400.0 million. Any future sales-based milestone payments will be expensed in the period in which the sales milestone is achieved.

Under the license agreement, profit on our sales of ABRAXANE™ in North America will be shared equally between American BioScience and us. The license agreement defines profit as ABRAXANE™ net sales less cost of goods sold, selling expenses (including pre-launch production and other expenses which we have expensed as incurred, but which will be accumulated and charged against first profit under the agreement) and an allocation of related general and administrative expenses. We will expense American BioScience's share of profit earned in our statements of income as an element of cost of sales. Any costs and expenses related to product recalls and product liability claims generally will be split equally between American BioScience and us and expensed as incurred. Pursuant to an agreement that we have with American BioScience, certain costs of any unsaleable ramp-up inventory of ABRAXANE™ that was manufactured in preparation for its launch will be shared equally between us and American BioScience.

In November 2001, along with the license agreement for ABRAXANE™, we also entered into a manufacturing agreement with American BioScience under which we agreed to manufacture ABRAXANE™ for American BioScience and its licensees for sales outside North America. Under this agreement, we have the right to manufacture ABRAXANE™ for sales worldwide. For sales outside of our licensed territories, we will charge American BioScience and its licensees a customary margin on our manufacturing costs based on whether the product will be used for clinical trials or commercial sale. The initial term of this agreement is ten years and may be extended for successive two-year terms by American BioScience.

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### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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. The most significant estimates in our consolidated financial statements are discussed below. Actual results could vary from those estimates.

#### *Revenue recognition*

We recognize revenue from the sale of a product when title and risk of loss have transferred to the customer, collection is reasonably assured and we have no further performance obligation. This is typically when the product is received by the customer. At the time of sale, as further described below, we reduce sales and provide for estimated chargebacks, contractual allowances or customer rebates, product returns and customer credits and cash discounts. Our methodology used to estimate and provide for these sales provisions was consistent across all periods presented. Historical Medicaid rebates issued have not been material. Accruals for sales provisions are presented in our financial statements as a reduction of net revenue and accounts receivable and, for contractual allowances, an increase in accrued liabilities. We regularly review information related to these estimates and adjust our reserves accordingly if, and when, actual experience differs from estimates.

We have extensive, internal historical information on chargebacks, rebates and customer returns and credits which we use as the primary factor in determining the related reserve requirements. As further described below, due to the nature of our generic injectable products and their primary use in hospital and clinical settings with generally consistent demand, we believe that this internal historical data, in conjunction with periodic review of available third-party data (as described below) and updated for any applicable changes in available information provides a reliable basis for such estimates. Additionally, we periodically purchase external data on wholesale inventory levels from our wholesale customers, pharmaceutical sales data from third-party market research organizations and our sales force regularly visits wholesale locations to review inventory stocking levels.

Sales to our three major wholesale customers comprised 89% of our 2004 net sales. We periodically review the wholesale supply levels of our significant products by reviewing inventory reports purchased or available from wholesalers, evaluating our unit sales volume, and incorporating data from third-party market research firms and periodic visits to wholesalers' warehouses. Based on these activities, we attempt to keep a consistent wholesale stocking level of approximately two- to six-weeks across our generic products. The buying patterns of our customers do vary from time to time, both from customer to customer and product to product, but we believe that historic wholesale stocking or speculative buying activity in our generic distribution channel has not had a significant impact on our historic sales comparisons or sales provisions. To date we have not entered into any inventory management agreements with any of our wholesale customers which would require us to pay a fee in connection with their distribution of our products or other services, possibly including sales data and other services and contractual rights for us, but we may be required to enter into such agreements in the future in order to maintain our relationships with such wholesalers. We are unable to ascertain the potential impact of any such agreements on our cost of sales, but do not believe that such agreements would result in a substantial change in wholesale stocking levels of our products as compared to current levels.

Our sales provisions totaled \$771.6 million, \$676.4 million and \$427.1 million in 2004, 2003 and 2002, respectively, and related reserves totaled \$124.4 million and \$77.5 million at December 31, 2004 and 2003, respectively.

#### *Chargebacks*

Following industry practice, we typically sell our products to independent pharmaceutical wholesalers at wholesale list price. The wholesaler in turn sells our products to an end user, normally a hospital or alternative healthcare facility, at a lower contractual price previously established between us and the end user via a group

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purchasing organization, or GPO. GPOs enter into collective purchasing contracts with pharmaceutical suppliers to secure more favorable product pricing on behalf of their end-user members.

Our initial sale to the wholesaler, and the resulting receivable, are recorded at our wholesale list price. However, as most of these selling prices will be reduced to a lower end-user contract price, at the time of sale revenue is reduced by, and a provision recorded for, the difference between the list price and estimated end-user contract price multiplied by the estimated wholesale units outstanding pending chargeback that will ultimately be sold under end-user contracts. When the wholesaler ultimately sells the product to the end user at the end-user contract price, the wholesaler charges us, a chargeback, for the difference between the list price and the end-user contract price and such chargeback is offset against our initial estimated contra asset. The most significant estimates inherent in the initial chargeback provision relate to wholesale units pending chargeback and the ultimate end-user contract-selling price. We base our estimation for these factors primarily on internal product-specific sales and chargeback processing experience, estimated wholesaler inventory stocking levels, current contract pricing and our expectation for future contract pricing changes.

Our net chargeback reserve totaled \$97.4 million and \$58.0 million at December 31, 2004 and 2003, respectively. The \$39.4 million increase in chargeback requirements during 2004 resulted from the 37% fourth-quarter 2004 sales increase and an increased proportion of new oncology products in the sales mix. Oncology products generally require a higher chargeback provision. The methodology we used to estimate and provide for chargebacks was consistent across all periods presented. Due to information constraints in the distribution channel, it has not been practical, and has not been necessary, for us to capture and quantify the impact of current versus prior year activity on the chargeback provision. We do review current year chargeback activity to determine whether material changes in the provision relate to prior period sales; such changes have not been material. A one-percent decrease in our estimated end-user contract-selling prices would reduce 2004 net sales by \$0.5 million and a one-percent increase in wholesale units pending chargeback at December 31, 2004 would decrease 2004 net sales by \$1.0 million.

### *Contractual allowances, returns and credits, cash discounts and bad debts*

Contractual allowances, generally rebates or administrative fees, are offered to certain wholesale customers, GPOs and end-user customers, consistent with pharmaceutical industry practices. Settlement of rebates and fees may generally occur from one to 15 months from date of sale. We provide a general provision for contractual allowances at the time of sale based on the historical relationship between sales and such allowances. Upon receipt of chargeback, due to the availability of product and customer specific information on these programs, we then establish a specific provision for fees or rebates based on the specific terms of each agreement. Our reserve for contractual allowances totaled \$11.4 million at December 31, 2004 and \$7.0 million at each of December 31, 2003 and 2002. A one-percent increase in the estimated rate of contractual allowances to sales at December 31, 2004 would increase the provision for contractual allowances by \$1.5 million. Contractual allowances are reflected in the financial statements as a reduction of net sales and as a current accrued liability.

Consistent with industry practice, our return policy permits our customers to return products within a window of time before and after the expiration of product dating. We provide for product returns and other customer credits at the time of sale by applying historical experience factors generally based on our historic data on credits issued by credit category or product, relative to related sales and we provide specifically for known outstanding returns and credits. Our reserve for customer credits and product returns totaled \$9.4 million, \$8.8 million and \$6.3 million at December 31, 2004, 2003 and 2002, respectively. At December 31, 2004, a one percent increase in the estimated reserve requirements for customer credits and product returns would have decreased 2004 net sales by \$1.2 million.

We generally offer our customer a standard cash discount for prompt payments and, from time-to-time, may offer a greater discount and extended terms in support of product launches or other promotional programs. Our wholesale customers typically pay within terms and a provision for cash discount is established at the time of sale based on the terms of sale.

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We establish a reserve for bad debts based on general and identified customer credit exposure. Our loss due to bad debts in the three-year period ending December 31, 2004 was less than \$0.1 million.

### *Inventories*

Inventories are valued at the lower of cost or market as determined under the first-in, first-out, or FIFO, method for both book and tax purposes. Inventories consist of products currently approved for marketing and may include certain products pending regulatory approval. We capitalize inventory costs associated with products prior to regulatory approval based on our judgment of probable future commercial success and realizable value. Such judgment incorporates our knowledge and best judgment of where the product is in the regulatory review process, our required investment in the product, market conditions, competing products and our economic expectations for the product post-approval relative to the risk of manufacturing the product prior to approval. If final regulatory approval for such products is denied or delayed, we may need to expense such previously capitalized costs. At December 31, 2004, raw materials included \$40.2 million of ABRAXANE™ related inventory and work in process inventory included \$7.7 million of commercial ABRAXANE™ inventory pending approval at the date of these financial statements. Commercial shipments of ABRAXANE™ commenced on February 7, 2005. In the event that the commercial launch of ABRAXANE™ does not create sufficient need for paclitaxel raw material, we anticipate that we would be able to recover a substantial portion of our investment in paclitaxel raw material inventory through its disposition in secondary markets. On March 11, 2004, we entered into an agreement with American BioScience under which the parties agreed to share certain costs of any unsaleable ramp-up inventory of ABRAXANE™.

We routinely review our inventory and establish reserves when the cost of the inventory is not expected to be recovered our product cost exceeds realizable market value. In instances where inventory is at or approaching expiry, is not expected to be saleable based on our quality and control standards or for which the selling price has fallen below cost, we reserve for any inventory impairment based on the specific facts and circumstances. In evaluating the market value of ABRAXANE™ work in process inventory pending regulatory approval as compared to its cost at December 31, 2004, we considered the market pricing and demand for competing products, our anticipated selling price for the products and the impending launch of the product. Provisions for inventory reserves are reflected in the financial statements as an element of cost of sales with inventories presented net of related reserves.

### *Expense recognition*

Cost of sales represents the costs of the products which we have sold and consists of labor, raw materials, components, packaging, quality assurance and quality control, shipping and manufacturing overhead costs and the cost of finished products purchased from third parties.

Research and development costs are expensed as incurred or consumed and consist primarily of salaries and other personnel-related expenses, as well as depreciation of equipment, allocable facility, raw material and production expenses and contract and consulting fees. We have invested and will continue to invest in research and development to expand our new product offerings and grow our business.

Selling, general and administrative expenses consist primarily of salaries, commissions and other personnel-related expenses, as well as costs for travel, trade shows and conventions, promotional material and catalogs, advertising and promotion, facilities, risk management and professional fees. We believe that our selling, general and administrative expenses will continue to increase in line with the growth of our core generic and proprietary business.

### *Stock-based compensation*

Stock-based compensation related to research and development costs and selling, general and administrative expenses are presented separately in our consolidated statements of operations. Stock-based compensation represents the difference between the exercise price of options granted and the deemed fair value of our common

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stock on the grant date in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related interpretations. We recognize stock-based compensation over the option vesting period, typically four years, primarily on an accelerated basis using the graded vesting method in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation*.

### *Rights and Other Variable Stock Option Plans*

We have recorded deferred stock-based compensation related to stock options granted to employees and outside directors with such expense related to the issuance of stock based compensation which was either performance-based or, prior to the date of our initial public offering, for which the exercise price was less than the estimated fair value of common stock on the grant date. Based upon the number of unvested options outstanding as of December 31, 2004, we expect to amortize approximately \$2.4 million of deferred stock-based compensation over future periods, including, in each of the next five fiscal years: \$0.8 million; \$0.5 million; \$0.4 million; \$0.3 million; and \$0.3 million, respectively.

### **RECENT ACCOUNTING PRONOUNCEMENTS**

On December 16, 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R). SFAS 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends Statement No. 95, *Statement of Cash Flows*. Generally, SFAS 123(R) requires all share-based payments to employees to be recognized in the income statement based on their estimated fair value at date of grant amortized over the grant's vesting period. Pro forma disclosure of such estimated fair value is no longer an alternative financial statement presentation.

SFAS 123(R) is effective for fiscal periods ending after July 1, 2005 and offers two alternate means of adoption, either: the "modified prospective" method in which compensation cost is recognized for awards granted after the effective date of the statement and outstanding, unvested awards granted prior to SFAS 123(R)'s effective date, or; a "modified retrospective" method which applies the modified prospective method, but allows companies to restate prior periods based on amounts calculated for pro forma disclosures under the original Statement 123 for either all prior periods presented or prior interim periods in the year of adoption.

We will adopt SFAS 123(R) in the third quarter of 2005 but have not yet determined which transition option we will apply. The adoption of SFAS 123(R) will significantly impact our results of operations, but will have no impact on our overall financial position. The impact of SFAS 123(R) on our results of operations cannot be accurately predicted at this time as it will depend on future market prices and equity grants. However, had we adopted SFAS 123(R) in prior periods, the impact of the standard on the past period would likely approximate the pro forma amounts calculated and disclosed under the original Statement 123. SFAS 123(R) also requires that the any tax benefit in excess of compensation cost, as calculated under the new standard, be reported in the statement of cash flows as a financing activity rather than an operating activity. This change will reduce reported net operating cash flow and will equally increase reported net financing cash flow in periods after adoption. While we cannot estimate what those amounts will be in the future, the amount of operating cash flows recognized in prior periods for such excess tax deductions were \$2.9 million, \$5.1 million, and \$2.4 million in 2004, 2003 and 2002, respectively.

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

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our activities without increasing risk. Some of the securities that we invest in may have interest rate risk. This means that a change in prevailing interest rates may cause the fair value of the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the prevailing rate and the prevailing rate later rises, the fair value of the principal amount of our investment will probably decline.

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To minimize this risk, we intend to maintain an investment portfolio of cash equivalents and short-term investments consisting of high credit quality securities, including commercial paper, government and non-government debt securities and money market funds. We do not use derivative financial instruments. The average maturity of the debt securities in which we invest has been less than 90 days and the maximum maturity has been three months. Because our investments are diversified and are of a short-term nature, a hypothetical one or two percentage point change in interest rates would not have a material effect on our consolidated financial statements.

We have operated primarily in the United States and the majority of our activities with our collaborators outside the United States to date have been conducted in U.S. dollars. Our more significant currency risks are denominated in the Canadian and Australian dollars and Swiss Franc. We do not believe we have a material exposure to foreign currency risk because of the relative stability of these currencies in relation to the U.S. dollar. A 10% adverse change in currency exchange rates of the Canadian or Australian dollars or Swiss Franc versus the U.S. dollar would not have a material effect on our consolidated results of operations, financial position, or cash flows. Accordingly, we have not had any material exposure to foreign currency exchange rate fluctuations.

### **Item 8. *Financial Statements and Supplementary Data***

The Consolidated Financial Statements and Financial Statement Schedule are included in Part III, Item 15 (a) (1) and (2) of this Annual Report on Form 10-K.

**Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Securities Exchange Act of 1934. Our 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 accounting principles generally accepted in the United States of America. Internal control over financial reporting includes those written policies and procedures that:

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

Internal control over financial reporting includes the controls themselves, monitoring and internal auditing practices and actions taken to correct deficiencies as identified.

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.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2004. 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*. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. Management reviewed the results of its assessment with the Audit Committee of our Board of Directors.

Based on this assessment, management believes that, as of December 31, 2004, our internal control over financial reporting is effective.

Our independent registered public accounting firm has issued an attestation report on management's assessment of our internal control over financial reporting. This report appears on the following page.

**Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting**

The Board of Directors and Shareholders of American Pharmaceutical Partners, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that American Pharmaceutical Partners, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). American Pharmaceutical Partners, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that American Pharmaceutical Partners, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, American Pharmaceutical Partners, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of American Pharmaceutical Partners, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of income, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004 of American Pharmaceutical Partners, Inc. and our report dated March 10, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Chicago, Illinois  
March 10, 2005

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of American Pharmaceutical Partners, Inc.

We have audited the accompanying consolidated balance sheets of American Pharmaceutical Partners, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of income, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule included in the Index at Item 15(a). These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of American Pharmaceutical Partners, Inc. and subsidiaries at December 31, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also, in our opinion the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of American Pharmaceutical Partners, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Chicago, Illinois  
March 10, 2005

**American Pharmaceutical Partners, Inc.**  
**Consolidated Balance Sheets**

	December 31,	
	2004	2003
	(in thousands, except share data)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,154	\$ 5,460
Short-term investments	66,475	53,165
Accounts receivable, less allowances for doubtful accounts of \$632 in 2004 and \$510 in 2003 and net chargebacks of \$97,382 in 2004 and \$57,989 in 2003	15,457	31,402
Inventories	151,035	110,384
Prepaid expenses and other current assets	6,492	7,340
Deferred income taxes	12,825	7,948
	253,438	215,699
Property, plant and equipment, net	106,410	77,340
Investment in Drug Source Co., LLC	6,256	5,166
Product license rights and other non-current assets, net of accumulated amortization of \$568 in 2004 and \$202 in 2003	6,816	3,027
Deferred financing costs, net of accumulated amortization of \$57 in 2004 and \$1,702 in 2003	413	2,553
	\$373,333	\$303,785
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 22,247	\$ 26,560
Accrued expenses	35,562	29,120
	57,809	55,680
Deferred income taxes	2,833	2,044
	60,642	57,724
Stockholders' equity:		
Common stock—\$.001 par value; 100,000,000 shares authorized, 77,284,831 and 76,514,964 shares issued in 2004 and 2003, respectively	77	77
Additional paid-in capital	212,399	201,009
Amounts due from American BioScience, Inc.	(21,603)	(21,132)
Deferred stock-based compensation	(2,385)	(1,309)
Retained earnings	180,243	123,550
Accumulated other comprehensive income	234	140
Less treasury stock, at cost and inclusive of fees, 6,646,398 common shares in 2004 and 2003	(56,274)	(56,274)
	312,691	246,061
	\$373,333	\$303,785

See accompanying notes.

**American Pharmaceutical Partners, Inc.**  
**Consolidated Statements of Income**

	Year ended December 31,		
	2004	2003	2002
	(in thousands, except per share data)		
Net sales	\$405,010	\$351,315	\$277,474
Cost of sales	189,301	159,938	140,512
Gross profit	215,709	191,377	136,962
Operating expenses:			
Research and development	25,797	22,507	14,474
Selling, general, and administrative	92,034	52,719	44,285
Milestone payment	10,000	—	—
Stock-based compensation	1,077	1,215	2,347
Equity in net income of Drug Source Company, LLC	(2,084)	(1,837)	(1,666)
Total operating expenses	126,824	74,604	59,440
Income from operations	88,885	116,773	77,522
Interest income (includes \$1,097, \$1,221 and \$1,244 from American BioScience, Inc. in 2004, 2003, and 2002, respectively)	1,790	1,758	2,135
Interest and other	144	537	(1,358)
Loss on early extinguishment of credit facility	(1,986)	—	—
Income before income taxes	88,833	119,068	78,299
Provision for income taxes	32,140	47,375	33,100
Net income	\$ 56,693	\$ 71,693	\$ 45,199
Income per common share:			
Basic	\$ 0.81	\$ 1.03	\$ 0.62
Diluted	\$ 0.78	\$ 0.99	\$ 0.60
Research and development costs include purchases from Drug Source Company, LLC as follows:	\$ 417	\$ 1,842	\$ 1,542
The composition of stock-based compensation is as follows:			
Research and development	\$ 41	\$ 70	\$ 195
Selling, general and administrative	1,036	1,145	2,152
	\$ 1,077	\$ 1,215	\$ 2,347

See accompanying notes.

**American Pharmaceutical Partners, Inc.**  
**Consolidated Statements of Stockholders' Equity**  
**Years Ended December 31, 2004, 2003 and 2002**

	Common Stock \$0.001 par value		Additional Paid-in Capital	Amounts Due from American BioScience, Inc.	Deferred Stock-based Compensation	Retained Earnings	Other Comprehensive Income (Loss)	Treasury Stock		Total
	Shares	Amount						Shares	Amount	
(In thousands, except share data)										
Balance at January 1, 2002	72,408,942	\$ 72	\$ 149,017	\$ (20,957)	\$ (4,713)	\$ 6,658	\$ (7)	—	\$ —	\$130,070
Exercise of over-allotment option, net of underwriting discount	2,025,000	2	20,086	—	—	—	—	—	—	20,088
Exercise of stock options	874,796	1	1,911	—	—	—	—	—	—	1,912
Issuance of stock for employee retirement and stock purchase plans	56,560	—	385	—	—	—	—	—	—	385
Grants of stock options, net of forfeitures	—	—	(389)	—	447	—	—	—	—	58
Amortization of deferred stock-based compensation	—	—	—	—	2,290	—	—	—	—	2,290
Net advances to American BioScience, Inc.	—	—	—	(1,610)	—	—	—	—	—	(1,610)
Payment by American BioScience, Inc. of share of liability to VivoRx, Inc., net of related deferred income taxes	—	—	14,640	—	—	—	—	—	—	14,640
Tax benefit of stock option exercises and license amortization	—	—	3,955	—	—	—	—	—	—	3,955
Comprehensive income:										
Net income	—	—	—	—	—	45,199	—	—	—	45,199
Foreign currency translation gain	—	—	—	—	—	—	(4)	—	—	(4)
Comprehensive income	—	—	—	—	—	—	—	—	—	45,195
Purchase of common stock	—	—	—	—	—	—	—	5,050,317	(36,275)	(36,275)
Balance at December 31, 2002	75,365,298	\$ 75	\$ 189,605	\$ (22,567)	\$ (1,976)	\$ 51,857	\$ (11)	5,050,317	\$(36,275)	\$180,708
Exercise of stock options	968,435	2	3,101	—	—	—	—	—	—	3,103
Issuance of stock for employee retirement and stock purchase plans	145,231	—	1,071	—	—	—	—	—	—	1,071
Grants of stock options, net of forfeitures	—	—	19	—	(19)	—	—	—	—	—
Grants of restricted stock, net of forfeitures	36,000	—	529	—	(529)	—	—	—	—	—
Amortization of deferred stock-based compensation	—	—	—	—	1,215	—	—	—	—	1,215
Net advances to American BioScience, Inc.	—	—	—	1,435	—	—	—	—	—	1,435
Tax benefit of stock option exercises and license amortization	—	—	6,684	—	—	—	—	—	—	6,684
Comprehensive income:										
Net income	—	—	—	—	—	71,693	—	—	—	71,693
Foreign currency translation gain	—	—	—	—	—	—	151	—	—	151
Comprehensive income	—	—	—	—	—	—	—	—	—	71,844
Purchase of common stock	—	—	—	—	—	—	—	1,596,081	(19,999)	(19,999)

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**American Pharmaceutical Partners, Inc.**  
**Consolidated Statements of Stockholders' Equity**  
**Years Ended December 31, 2004, 2003 and 2002 (continued)**

	Common Stock \$0.001 par value		Additional Paid-in Capital	Amounts Due from American BioScience, Inc.	Deferred Stock-based Compensation	Retained Earnings	Other Comprehensive Income (Loss)	Treasury Stock		Total
	Shares	Amount						Shares	Amount	
	(In thousands, except share data)									
Balance at December 31, 2003	76,514,964	\$ 77	\$ 201,009	\$ (21,132)	\$ (1,309)	\$ 123,550	\$ 140	6,646,398	\$ (56,274)	\$ 246,061
Exercise of stock options	467,075	—	2,224	—	—	—	—	—	—	2,224
Issuance of stock for employee retirement and stock purchase plans	242,792	—	2,440	—	—	—	—	—	—	2,440
Grants of stock options, net of forfeitures	—	—	273	—	(273)	—	—	—	—	—
Grants of restricted stock	60,000	—	1,759	—	(1,759)	—	—	—	—	—
Amortization of deferred stock-based compensation	—	—	121	—	956	—	—	—	—	1,077
Net advances to American BioScience, Inc.	—	—	—	(471)	—	—	—	—	—	(471)
Tax benefit of stock option exercises and license amortization	—	—	4,573	—	—	—	—	—	—	4,573
Comprehensive income:										
Net income	—	—	—	—	—	56,693	—	—	—	56,693
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	—	563	—	—	563
Foreign currency translation loss, net of tax	—	—	—	—	—	—	(469)	—	—	(469)
Comprehensive income	—	—	—	—	—	—	—	—	—	56,787
Balance at December 31, 2004	77,284,831	\$ 77	\$ 212,399	\$ (21,603)	\$ (2,385)	\$ 180,243	\$ 234	6,646,398	\$ (56,274)	\$ 312,691

See accompanying notes.

**American Pharmaceutical Partners, Inc.**  
**Consolidated Statements of Cash Flows**

	Years Ended December 31,		
	2004	2003	2002
	(in thousands)		
<b>Cash flows from operating activities:</b>			
Net income	\$ 56,693	\$ 71,693	\$ 45,199
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	8,791	8,039	9,069
Amortization	986	963	911
Imputed interest on liability to Vivo Rx, Inc.	—	—	1,314
Stock-based compensation	1,077	1,215	2,347
Loss on early extinguishment of credit facility	1,986	—	—
Loss on disposal of property, plant and equipment	32	6	31
Deferred income taxes	(4,088)	1,998	(3,281)
Equity in net income of Drug Source Company, LLC in excess of dividends received	(1,090)	(1,988)	(1,666)
Tax benefit on stock option exercises	2,888	5,125	2,355
Changes in operating assets and liabilities:			
Accounts receivable, net	15,945	(10,124)	(5,629)
Inventories	(40,651)	(32,648)	(26,483)
Prepaid expenses and other current assets	848	(3,730)	(1,141)
Accounts payable and accrued expenses	3,814	16,976	14,837
Net cash provided by operating activities	47,231	57,525	37,863
<b>Cash flows from investing activities:</b>			
Purchases of property, plant and equipment	(37,893)	(22,753)	(17,916)
Purchase of product license rights and other	(3,588)	(1,679)	(1,250)
Net (purchases) of short-term investments	(13,310)	(53,165)	—
Net cash used in investing activities	(54,791)	(77,597)	(19,166)
<b>Cash flows from financing activities:</b>			
Proceeds from exercise of stock options	2,224	3,103	1,912
Proceeds from sale of stock under employee retirement and stock purchase plans	2,440	1,071	385
Payment of license fee to American BioScience, Inc.	—	—	(60,000)
(Increase) decrease in amounts due from American BioScience, Inc.	(471)	1,435	(1,610)
Payment of deferred financing costs	(470)	—	(110)
Proceeds from sale of common stock, net	—	—	20,088
Purchase of treasury stock, net	—	(19,999)	(36,275)
Net cash provided by (used in) financing activities	3,723	(14,390)	(75,610)
Effect of foreign currency translation	(469)	151	(4)
Increase in cash and cash equivalents	(4,306)	(34,311)	(56,917)
Cash and cash equivalents at beginning of period	5,460	39,771	96,688
Cash and cash equivalents at end of period	\$ 1,154	\$ 5,460	\$ 39,771
<b>Supplemental disclosure of cash flow information</b>			
Cash paid for:			
Interest	\$ —	\$ 6	\$ 10
Income taxes (including in lieu of payments to American BioScience, Inc.)	21,413	36,684	32,567
<b>Supplemental disclosure of noncash investing and financing activities</b>			
Payment by American BioScience, Inc. of share of liability to Vivo Rx, Inc., net of related deferred tax asset of \$—, \$—, and \$9,360 in 2004, 2003 and 2002, respectively	\$ —	\$ —	\$ 14,640

See accompanying notes.

**American Pharmaceutical Partners, Inc.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2004**

**1. Description of Business**

Incorporated in Delaware in 2001, as successor to a California corporation formed in 1996, American Pharmaceutical Partners, Inc. is a majority owned subsidiary of American BioScience, Inc., a California corporation. At December 31, 2004, American BioScience owned 47,984,160 shares, or 67.9%, of our outstanding common stock.

We are a pharmaceutical company that develops, manufactures and markets injectable pharmaceutical products. We believe that we are the only independent U.S. public company with a primary focus on the injectable oncology, anti-infective and critical care markets, and we further believe that we offer one of the most comprehensive injectable product portfolios in the pharmaceutical industry. We manufacture products in each of the three basic forms in which injectable products are sold: liquid, powder and lyophilized, or freeze-dried.

We began in 1996 with an initial focus on U.S. marketing and distribution of generic pharmaceutical products manufactured by others. In June 1998, we acquired Fujisawa USA, Inc.'s generic injectable pharmaceutical business including manufacturing facilities in Melrose Park, Illinois and Grand Island, New York and our research and development facility in Melrose Park, Illinois. We also acquired additional assets in this transaction, including inventories, plant and equipment and abbreviated new drug applications that were approved by or pending with the U.S. Food and Drug Administration, or FDA.

Our products are generally used in hospitals, long-term care facilities, alternate care sites and clinics within North America. Unlike the retail pharmacy market for oral products, the injectable pharmaceuticals marketplace is largely made up of end users who have relationships with group purchasing organizations, or GPOs, and/or specialty distributors who distribute products within a particular end-user market, such as oncology clinics. GPOs and specialty distributors generally enter into collective product purchasing agreements with pharmaceutical suppliers in an effort to secure more favorable drug pricing on behalf of their members.

We hold the exclusive North American right to sell ABRAXANE™, a proprietary nanoparticle injectable oncology product that is a patented formulation of paclitaxel. Paclitaxel is the active ingredient in Taxol®, one of the world's top selling cancer drugs. In January 2005, we announced that American BioScience's New Drug Application, or NDA, for ABRAXANE™ had been approved by the FDA and we launched the product on February 7, 2005. ABRAXANE™, consists only of albumin-bound paclitaxel nanoparticles, is free of toxic solvents and demonstrated a superior response rate with an almost doubling of the reconciled target lesion response rate when compared with the solvent-based Taxol® in a prospectively randomized trial of 460 patients with metastatic breast cancer. Because it contains no toxic solvents, this next-generation taxane product enables the administration of 50% more chemotherapy with a well-tolerated safety profile, requires no routine premedication to prevent hypersensitivity reactions and can be given over a shorter infusion time using standard IV tubing.

**2. Summary of Significant Accounting Policies**

*Basis of Consolidation*

The consolidated financial statements include the assets, liabilities, and results of operations of American Pharmaceutical Partners, Inc., our wholly owned subsidiary Pharmaceutical Partners of Canada, Inc. and our investment in Drug Source Company, LLC, which is accounted for using the equity method. All material intercompany balances and transactions have been eliminated in consolidation. Certain previously reported amounts have been reclassified to conform to the current period presentation.

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A wholly owned subsidiary of American Pharmaceutical Partners holds a 50% interest in Drug Source Company. Drug Source Company is a joint venture with three other partners established in June 2000 to purchase raw materials for resale to pharmaceutical companies, including us. Because our 50% interest in Drug Source Company does not provide financial or operational control of the entity, we account for our interest in Drug Source Company under the equity method. Our equity in the net income of Drug Source Company, net of intercompany profit on purchases of inventory, is classified in operating expenses in the accompanying consolidated statements of income. Research and development expense included purchases from Drug Source Company of \$0.4 million, \$1.8 million and \$1.5 million in 2004, 2003 and 2002, respectively. Ending inventory included purchases from Drug Source Company of \$2.9 million and \$0.8 million at December 31, 2004 and 2003, respectively.

### *Fiscal Year*

We use a 52-week or 53-week fiscal year that ends on the Saturday nearest to December 31. For clarity of presentation, all periods are presented as if the year ended on December 31. The fiscal year ended December 31, 2004, contained 53 weeks and the fiscal years ended December 31, 2003, and 2002 contained 52 weeks.

### *Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates may also affect the reported amounts of revenues and expenses during the reporting period. We routinely estimate chargeback liabilities and other sales allowances. Actual results could differ from those estimates.

### *Cash, Cash Equivalents and Short-term Investments*

It is our policy to include cash and investments having a maturity of three months or less at the time of acquisition in cash and cash equivalents. Short-term investments consist of highly-liquid, available-for-sale, municipal variable rate demand notes, which are recorded at cost, and may be redeemed at par upon seven days notice. The cost of these short-term investments closely approximates their fair market value due to their variable interest rates, which typically reset every seven days. All securities held had maturities of greater than 10 years. We have never incurred realized or unrealized holding gains or losses on these securities and income resulting from our short-term investments is recorded as interest income.

### *Accounts Receivable and Concentration of Credit Risk*

We typically have multi-year contractual agreements with GPOs and individual hospital groups to supply our products to end-user hospital and alternate site customers. As is traditional in the pharmaceutical industry, a significant amount of our generic pharmaceutical products are sold to end users under GPO contracts through a relatively small number of drug wholesalers, which comprise the primary pharmaceutical distribution chain in the United States. Three wholesalers collectively, and approximately proportionately, represented 89%, 87% and 92% of our sales in fiscal 2004, 2003 and 2002, respectively, and represented 86% and 89% of accounts receivable at December 31, 2004 and 2003, respectively. To help control our credit exposure, we routinely monitor the creditworthiness of our customers, review outstanding customer balances on a regular basis and record allowances for bad debts as necessary. We insure all, or a portion of, gross receivables from our largest customers to protect against risk of significant credit loss. Historical credit loss has been insignificant.

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### Inventories

Inventories are valued at the lower of cost or market as determined under the first-in, first-out, or FIFO, method for both book and tax purposes, as follows:

	December 31,					
	2004			2003		
	Approved	Pending Regulatory Approval	Total Inventory	Approved	Pending Regulatory Approval	Total Inventory
	(in thousands)					
Finished goods	\$ 36,706	\$ —	\$ 36,706	\$ 30,300	\$ —	\$ 30,300
Work in process	16,888	7,674	24,562	15,948	—	15,948
Raw materials	49,563	40,204	89,767	36,536	27,600	64,136
	<u>\$ 103,157</u>	<u>\$ 47,878</u>	<u>\$ 151,035</u>	<u>\$ 82,784</u>	<u>\$ 27,600</u>	<u>\$ 110,384</u>

Inventories consist of products currently approved for marketing and may include certain products pending regulatory approval. We capitalize inventory costs associated with products prior to regulatory approval based on our judgment of probable future commercial success and realizable value. Such judgment incorporates our knowledge and best judgment of where the product is in the regulatory review process, our required investment in the product, market conditions, competing products and our economic expectations for the product post-approval relative to the risk of manufacturing the product prior to approval. If final regulatory approval for such products is denied or delayed, we may need to expense such previously capitalized costs. At each of December 31, 2003 and 2004, our investment in inventory pending regulatory approval consisted solely of ABRAXANE™ related inventory pending approval at the date of these financial statements. Commercial shipments of ABRAXANE™ commenced on February 7, 2005. In the event that the commercial launch of ABRAXANE™ does not create sufficient need for paclitaxel raw material, we anticipate that we would be able to recover a substantial portion of our investment in paclitaxel raw material inventory through its disposition in secondary markets. On March 11, 2004, we entered into an agreement with American BioScience under which the parties agreed to share certain costs of any unsaleable ramp-up inventory of ABRAXANE™.

We routinely review our inventory and establish reserves when the cost of the inventory is not expected to be recovered or our product cost exceeds realizable market value. In instances where inventory is at or approaching expiry, is not expected to be saleable based on our quality and control standards or for which the selling price has fallen below cost, we reserve for any inventory impairment based on the specific facts and circumstances. In evaluating the market value of ABRAXANE™ work in process inventory pending regulatory approval as compared to its cost at December 31, 2004, we considered the market, pricing and demand for competing products, our anticipated selling price for the product and the impending launch of the product. Provisions for inventory reserves are reflected in the financial statements as an element of cost of sales with inventories presented net of related reserves.

### Property, Plant and Equipment

Property, plant and equipment is stated on the basis of cost or allocated acquisition value. Provisions for depreciation are computed for financial reporting purposes using the straight-line method over the lesser of the estimated useful life of the related asset or, for leasehold improvements, the term of the related lease as follows:

Buildings and improvements	10–30 years
Machinery and equipment	3–10 years
Furniture and fixtures	5–7 years

Depreciation expense was \$8.8 million, \$8.0 million and \$9.1 million for the years ended December 31, 2004, 2003 and 2002, respectively. Depreciation expense increased \$0.8 million in 2004, as compared to 2003, due primarily to the impact of capital expenditures made in 2004 and 2003.

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Property, plant, and equipment consist of the following:

	December 31,	
	2004	2003
	(in thousands)	
Land	\$ 3,847	\$ 2,589
Building and improvements	55,039	37,376
Machinery and equipment	52,497	41,979
Furniture and fixtures	13,502	9,621
Construction in progress	37,775	28,844
	<u>162,660</u>	<u>120,409</u>
Less allowance for depreciation	(56,250)	(43,069)
	<u>\$106,410</u>	<u>\$ 77,340</u>

The 2004 increase in property, plant and equipment resulted from the purchase of certain assets, including a manufacturing facility in Switzerland in the 2004 third quarter, and a higher level of capital expenditures supporting additional or improved manufacturing capacity and information technology initiatives. We are implementing a new enterprise resource planning, or ERP, business system application during 2003 and 2004 and have entered into various related licensing and support agreements. At December 31, 2004 and 2003, \$17.1 million and \$13.2 million, respectively, was included in construction in process related to software license fees, hardware and other implementation costs related to this project.

### *Deferred Financing Costs*

In the third quarter of 2004, we recorded a non-cash, pretax charge of \$2.0 million to write-off unamortized debt acquisition costs related to the early extinguishment of our prior five-year credit facility in 2002. The \$2.6 million in deferred financing costs at December 31, 2003 related to costs incurred in connection with obtaining the prior facility. The \$0.4 million of costs incurred in obtaining the new \$100 million facility in September 2004 have been deferred and are being amortized on a straight-line basis over the new facility's three-year term. Deferred financing costs are stated net of accumulated amortization in the consolidated balance sheets.

### *Product Rights and Other Assets*

In October 2003, in connection with a development and commercialization agreement for a low-molecular weight heparin product, we acquired \$1.25 million of the preferred stock of an Australian company, Alchemia Limited, and agreed, in the future, to contribute additional equity investment up to \$1.25 million and to offer a U.S. dollar denominated interest-free loan to Alchemia of up to \$1.25 million in relation to process scale-up work, with the loan convertible at our option into equity of Alchemia.

Our investment in Alchemia common shares has been classified as an available-for-sale marketable equity security and was recorded at fair market value with any unrealized holding gains or losses, net of tax, included in accumulated other comprehensive income. In late 2003, Alchemia underwent an initial public offering on the Australian Stock Exchange, and our initial investment in preferred stock converted to common stock. During 2004, we invested an additional \$1.25 million in Alchemia common stock. At December 31, 2004, the total cost of our investment in Alchemia was \$2.5 million with the fair market value recorded on our books at \$3.6 million due primarily to market appreciation. We monitor our investment in Alchemia for other than temporary declines in fair value and would charge any future impairment loss to income should an other than temporary decline in estimated value occur. At December 31, 2004, \$0.5 million was outstanding under the note receivable.

In July 2003, we acquired from Eli Lilly Canada Inc. the Canadian market and trademark rights for four proprietary products, Tazidime<sup>®</sup>, or ceftazidime, Kefurox<sup>®</sup>, or cefuroxime, Kefzol<sup>®</sup>, or cefazolin, Dobutrex<sup>®</sup>, or dobutamine, as well as the Canadian market rights for injectable vancomycin, for \$0.3 million. In December 2003, we also obtained the Canadian market rights to tobramycin from Eli Lilly Canada. These rights will be amortized over the estimated life of the agreements.

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Product license rights are stated net of accumulated amortization in the consolidated balance sheets. The aggregate amortization expense related to product rights was \$0.4 million, \$0.1 million and \$0.1 million for the years ended December 31, 2004, 2003 and 2002, respectively. Estimated aggregate amortization expense based on the current carrying value of amortizable product and intellectual property rights will be approximately \$0.4 million, \$0.3 million, \$0.3 million, \$0.3 million and \$0.1 million, for each of the next five years, respectively.

### *Revenue recognition*

We recognize revenue from the sale of a product when title and risk of loss have transferred to the customer, collection is reasonably assured and we have no further performance obligation. This is typically when the product is received by the customer. At the time of sale, as further described below, we reduce sales and provide for estimated chargebacks, contractual allowances or customer rebates, product returns and customer credits and cash discounts. The methodology we used to estimate and provide for these sales provisions was consistent across all periods presented. Historical Medicaid rebates have not been material. Accruals for sales provisions are presented in our financial statements as a reduction of net revenue and accounts receivable and, for contractual allowances, an increase in accrued liabilities.

We have extensive, internal historical information on chargebacks, rebates and customer returns and credits which we use as the primary factor in determining the related reserve requirements. As further described below, due to the nature of our generic injectable products and their primary use in hospital and clinical settings with generally consistent demand, we believe that this internal historical data, in conjunction with periodic review of available third-party data (as described below) and updated for any applicable changes in available information provides a reliable basis for such estimates. Additionally, we periodically purchase external data on wholesale inventory levels from our wholesale customers, pharmaceutical sales data from third-party market research organizations and our sales force regularly visits wholesale locations to review inventory stocking levels.

Sales to our three major wholesale customers comprised 89% of our 2004 net sales. We periodically review the wholesale supply levels of our significant products by reviewing inventory reports purchased or available from wholesalers, evaluating our unit sales volume, and incorporating data from third-party market research firms and periodic visits to wholesalers' warehouses. Based on these activities, we attempt to keep a consistent wholesale stocking level of approximately two to six weeks across our generic products. The buying patterns of our customers do vary from time to time, both from customer to customer and product to product, but we believe that historic wholesale stocking or speculative buying activity in our generic distribution channel has not had a significant impact on our historic sales comparisons or sales provisions. To date we have not entered into any inventory management agreements with any of our wholesale customers which would require us to pay a fee in connection with their distribution of our products or other services, possibly including sales data and other services and contractual rights for us, but we may be required to enter into such agreements in the future in order to maintain our relationships with such wholesalers. We are unable to ascertain the potential impact of any such agreements on our cost of sales, but do not believe that such agreements would result in a substantial change in wholesale stocking levels of our products as compared to current levels.

Our sales provisions totaled \$771.6 million, \$676.4 million and \$427.1 million in 2004, 2003 and 2002, respectively, and related reserves totaled \$124.4 million and \$77.5 million at December 31, 2004 and 2003, respectively.

### *Chargebacks*

Following industry practice, we typically sell our products to independent pharmaceutical wholesalers at wholesale list price. The wholesaler in turn sells our products to an end user, normally a hospital or alternative healthcare facility, at a lower contractual price previously established between us and the end user via a group purchasing organization, or GPO. GPOs enter into collective purchasing contracts with pharmaceutical suppliers to secure more favorable product pricing on behalf of their end-user members.

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Our initial sale to the wholesaler, and the resulting receivable, are recorded at our wholesale list price. However, as most of these selling prices will be reduced to a lower end-user contract price, at the time of sale revenue is reduced by, and a provision recorded for, the difference between the list price and estimated end-user contract price multiplied by the estimated wholesale units outstanding pending chargeback that will ultimately be sold under end-user contracts. When the wholesaler ultimately sells the product to the end user at the end-user contract price, the wholesaler charges us, a chargeback, for the difference between the list price and the end-user contract price and such chargeback is offset against our initial estimated contra asset. The most significant estimates inherent in the initial chargeback provision relate to wholesale units pending chargeback and the ultimate end-user contract-selling price. We base our estimation for these factors primarily on internal, product-specific sales and chargeback processing experience, estimated wholesaler inventory stocking levels, current contract pricing and our expectation for future contract pricing changes. Chargeback activity for the three years ended December 31, 2004 was as follows:

	Year Ended December 31,		
	2004	2003	2002
		(in thousands)	
Balance at beginning of year	\$ 57,989	\$ 50,212	\$ 19,271
Provision for chargebacks	674,820	610,763	383,168
Credits or checks issued to third parties	(635,427)	(602,986)	(352,227)
Other	—	—	—
Balance at end of year	\$ 97,382	\$ 57,989	\$ 50,212

The \$39.4 million increase in chargeback requirements during 2004 resulted from the 37% fourth-quarter 2004 sales increase and an increased proportion of new oncology products in the sales mix. Oncology products generally require a higher chargeback provision. Our methodology used to estimate and provide for chargebacks was consistent across all periods presented. Due to information constraints in the distribution channel, it has not been practical, and has not been necessary, for us to capture and quantify the impact of current versus prior year activity on the chargeback provision. We do review current year chargeback activity to determine whether material changes in the provision relate to prior period sales: such changes have not been material. A one-percent decrease in our estimated end-user contract-selling prices would reduce 2004 net sales by \$0.5 million and a one-percent increase in wholesale units pending chargeback at December 31, 2004 would decrease 2004 net sales by \$1.0 million.

### *Contractual allowances, returns and credits, cash discounts and bad debts*

Contractual allowances, generally rebates or administrative fees, are offered to certain wholesale customers, GPOs and end-user customers, consistent with pharmaceutical industry practices. Settlement of rebates and fees may generally occur from one to 15 months from date of sale. We provide a general provision for contractual allowances at the time of sale based on the historical relationship between sales and such allowances. Upon receipt of chargeback, due to the availability of product and customer specific information on these programs, we then establish a specific provision for fees or rebates based on the specific terms of each agreement. A one percent increase in the estimated rate of contractual allowances to sales at December 31, 2004 would increase the provisions for contractual allowances by \$1.5 million. Contractual allowances are reflected in the financial statements as a reduction of net sales and as a current accrued liability. Our provision for contractual allowances during each of the three years ended December 31, 2004 was as follows:

	Year Ended December 31,		
	2004	2003	2002
		(in thousands)	
Balance at beginning of year	\$ 6,988	\$ 6,919	\$ 2,295
Provision for contractual allowances and customer rebates	27,116	19,861	15,263
Credits issued to third parties	(22,671)	(19,792)	(10,639)
Other	—	—	—
Balance at end of year	\$ 11,433	\$ 6,988	\$ 6,919

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Consistent with industry practice, our return policy permits our customers to return products within a window of time before and after the expiration of product dating. We provide for product returns and other customer credits at the time of sale by applying historical experience factors, generally based on our historic data on credits issued by credit category or product, relative to related sales and we provide specifically for known outstanding returns and credits. At December 31, 2004, a one-percent increase in the estimated reserve requirements for customer credits and product returns would have decreased 2004 net sales by \$1.2 million. Our provision for contractual allowances during each of the three years ended December 31, 2004 was as follows:

	Year Ended December 31,		
	2004	2003	2002
	(in thousands)		
Balance at beginning of year	\$ 8,820	\$ 6,346	\$ 5,061
Provision for customer credits and product returns	28,248	25,879	15,578
Credits issued to third parties	(27,671)	(23,405)	(14,293)
Other	—	—	—
Balance at end of year	\$ 9,397	\$ 8,820	\$ 6,346

We generally offer our customer a standard cash discount for prompt payments and, from time-to-time, may offer a greater discount and extended terms in support of product launches or other promotional programs. Our wholesale customers typically pay within terms and a provision for cash discount is established at the time of sale based on the terms of sale.

We establish a reserve for bad debts based on general and identified customer credit exposure. Our loss due to bad debts in the three-year period ending December 31, 2004 was less than \$0.1 million.

### Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases as well as net operating loss and capital loss carry forwards. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the consolidated financial statements in the period that includes the legislative enactment date.

Since our December 2001 initial public offering, we have filed separate, stand-alone federal income tax returns. For state purposes, depending on applicable state laws, we may file a separate return or a consolidated tax return with American BioScience. All allocated income taxes have been accounted for through the intercompany account with American BioScience.

### Research and Development Costs

Costs relating to the research and development of new products or production capabilities are charged to expense as incurred.

### Stock-Based Compensation

As permitted by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-based Compensation*, or SFAS 123, as amended by No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*, we account for stock options granted to our employees and outside directors and stock purchase rights issued to employees using the intrinsic value method of accounting, as prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Under the intrinsic

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value method, no compensation expense is recorded if the exercise price of our stock options is equal to or greater than the market price of the underlying stock on the date of grant. Our stock-based compensation expense results from the issuance of stock based compensation which was either performance-based or, prior to the date of our initial public offering, for which the exercise price was less than the estimated fair value of common stock on the grant date. For these stock options, we recorded deferred stock-based compensation for the difference between the exercise price and estimated fair value on the date of grant. The excess of fair market value over the exercise price is amortized to expense, primarily on an accelerated basis, using the graded vesting method over the stock options' vesting period.

Had compensation cost for grants of stock-based compensation been determined using the fair value method of accounting as prescribed by SFAS 123, our net income and income per share would have been reduced to the pro forma amounts indicated below:

	Year Ended December 31,		
	2004	2003	2002
	(in thousands, except per share data)		
Net income, as reported	\$56,693	\$71,693	\$45,199
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	666	731	1,338
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(6,064)	(3,695)	(2,247)
<b>Pro forma net income</b>	<b>\$51,295</b>	<b>\$68,729</b>	<b>\$44,290</b>
<b>Net income per common share:</b>			
Basic—as reported	\$ 0.81	\$ 1.03	\$ 0.62
Basic—pro forma	\$ 0.73	\$ 0.99	\$ 0.61
Diluted—as reported	\$ 0.78	\$ 0.99	\$ 0.60
Diluted—pro forma	\$ 0.70	\$ 0.94	\$ 0.59

This pro forma disclosure is not likely to be indicative of pro forma results that may be expected in future years because options vest over several years, pro forma compensation expense is recognized as the options vest and additional awards may also be granted.

For purposes of determining the pro forma effect under SFAS 123 of stock options granted to employees and directors and stock purchase rights issued under our employee stock purchase plan, or ESPP, the fair value of each option or right is estimated on the date of grant based on the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2004	2003	2002
<b>Stock Options</b>			
Risk-free rate	3.4%	2.9%	3.6%
Dividend yield	—	—	—
Expected life in years	5	5	5
Volatility	69%	67%	72%
<b>Employee Stock Purchase Plan</b>			
Risk-free rate	1.9%	1.7%	1.7%
Dividend yield	—	—	—
Expected life in years	1.4	1.4	0.7
Volatility	69%	67%	72%

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### Fair Value of Financial Instruments

Our financial instruments consist mainly of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and our credit facility. Cash equivalents include investments with maturities of three months or less at the time of acquisition. Short-term investments consist of highly-liquid, available-for-sale, municipal variable rate demand notes, which are recorded at cost, and may be redeemed at par upon seven days notice. The carrying value of substantially all our financial instruments approximates their fair value due to the short-term nature of these financial instruments. The interest rates on borrowings under our bank credit facility are revised periodically to reflect market rate fluctuations.

We have not used any derivatives or other foreign currency or interest rate hedging instruments and, accordingly, Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities*, has had no effect on our consolidated financial statements.

### Per Share Information

Basic income per common share is computed by dividing net income by the weighted-average number of common shares outstanding. Dilutive income per common share is computed by dividing net income by the weighted-average number of common shares used for the basic calculations plus potentially dilutive shares for the portion of the year that the shares were outstanding. Potentially dilutive common shares resulted from outstanding stock option. Calculations of basic and diluted income per common share information are based on the following:

	Year ended December 31,		
	2004	2003	2002
	(in thousands, except per share data)		
Basic and dilutive numerator:			
Net income	\$56,693	\$71,693	\$45,199
Denominator:			
Weighted-average common shares outstanding—Basic	70,305	69,673	72,711
Net effect of dilutive securities:			
Stock options	2,842	3,072	2,768
Weighted common shares—Diluted	73,147	72,745	75,479
Income per common share—Basic	\$ 0.81	\$ 1.03	\$ 0.62
Income per common share—Diluted	\$ 0.78	\$ 0.99	\$ 0.60

Employee stock options for which the exercise price exceeded the average market price of our common stock in the respective fiscal years were excluded from the computation of diluted income per common share as follows:

	Year ended December 31,		
	2004	2003	2002
	(in thousands, except per share data)		
Number of shares excluded	339	76	200
Range of exercise prices	\$33.38–\$46.20	\$28.51–\$38.37	\$16.00–\$19.30

### Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R). SFAS 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends Statement No. 95, *Statement of*

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*Cash Flows.* Generally, SFAS 123(R) requires all share-based payments to employees to be recognized in the income statement based on their estimated fair value at date of grant amortized over the grant's vesting period. Pro forma disclosure of such estimated fair value is no longer an alternative financial statement presentation.

SFAS 123(R) is effective for fiscal periods ending after July 1, 2005 and offers two alternate means of adoption, either: the "modified prospective" method in which compensation cost is recognized for awards granted after the effective date of the statement and outstanding, unvested awards granted prior to SFAS 123(R)'s effective date, or; a "modified retrospective" method which applies the modified prospective method, but allows companies to restate prior periods based on amounts calculated for pro forma disclosures under the original Statement 123 for either all prior periods presented or prior interim periods in the year of adoption.

We will adopt SFAS 123(R) in the third quarter of 2005 but have not yet determined which transition option we will apply. The adoption of SFAS 123(R) will significantly impact our results of operations, but will have no impact on our overall financial position. The impact of SFAS 123(R) on our results of operations cannot be accurately predicted at this time as it will depend on future market prices and equity grants. However, had we adopted SFAS 123(R) in prior periods, the impact of the standard on the past period would likely approximate the pro forma amounts calculated and disclosed under the original Statement 123. SFAS 123(R) also requires that the any tax benefit in excess of compensation cost, as calculated under the new standard, be reported in the statement of cash flows as a financing activity rather than an operating activity. This change will reduce reported net operating cash flow and will equally increase reported net financing cash flow in periods after adoption. While we cannot estimate what those amounts will be in the future, the amount of operating cash flows recognized in prior periods for such excess tax deductions were \$2.9 million, \$5.1 million, and \$2.4 million in 2004, 2003 and 2002, respectively.

### **3. Transactions with American BioScience**

#### *Product License and Manufacturing Agreements*

We hold the exclusive North American marketing rights and the worldwide manufacturing rights for ABRAXANE™. The FDA approved ABRAXANE™, for the filed indication on January 7, 2005 and ABRAXANE™ was launched on February 7, 2005. ABRAXANE™ is licensed from American BioScience, which is responsible for conducting the clinical studies of and obtaining regulatory approval for ABRAXANE™.

In November 2001, we signed a perpetual license agreement with American BioScience under which we acquired the exclusive rights to market and sell ABRAXANE™ in North America for indications relating to breast, lung, ovarian, prostate and other cancers. Under the agreement, we made an initial payment to American BioScience of \$60.0 million and committed to future milestone payments contingent upon achievement of specified regulatory, publication and sales objectives for licensed indications. American BioScience is responsible for conducting clinical studies in support of ABRAXANE™ and for substantially all costs associated with the development and obtaining regulatory approval for ABRAXANE™, except that we provided \$2.0 million of ABRAXANE™ for use in clinical trials, the cost of which we charged to research and development expense in 2001. Any profit, as defined in the license agreement, resulting from our sales of ABRAXANE™ will be shared equally between American BioScience and us, following the recapture of half of the pre-launch sales, marketing and pre-production start-up costs we have incurred.

The terms of the license agreement were negotiated to reflect the value of the licensed product rights acquired, then in late-stage development, American BioScience's remaining obligation to complete the NDA filing and the potential sales of the product under licensed clinical indications. The license agreement was a product of several months of extensive negotiation with American BioScience involving outside counsel, investment banks and a nationally recognized valuation firm. Based upon the analysis and recommendations of our advisors, we believe that the overall terms of the agreement were fair to us, including in comparison to similar licenses between unrelated parties. The agreement was unanimously approved by the disinterested members of our Board of Directors, with those directors who also have an affiliation with American BioScience

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recusing themselves from the vote. There are no restrictions on how American BioScience would use payments made under the license agreement and we understand such payments have been and will be used both to fund the development of ABRAXANE™ in relation to our licensed product rights and for other purposes.

In December 2001, in conjunction with our initial public offering, we recorded an initial payment due American BioScience of \$60.0 million. In our financial statements, the license agreement was accounted for as an asset contributed by a principal shareholder using the shareholder's historical cost basis, which was zero, and the \$60.0 million payment was accounted for as a distribution of stockholders' equity. For income tax purposes, the payment was recorded as an asset and is being amortized over a 15-year period. Because there was no corresponding charge to income, the income tax benefit of this payment is being credited to stockholders' equity as realized.

Under the license agreement, American BioScience earned milestone payments upon the filing and approval of ABRAXANE™ for metastatic breast cancer indication. The first such milestone of \$10.0 million was achieved in May 2004 when the FDA accepted American BioScience's NDA for the metastatic breast cancer indication. This payment was expensed and paid in the second quarter of 2004. The FDA then approved ABRAXANE™ for the filed indication in January 2005, triggering a \$15.0 million milestone payment in the first quarter of 2005, which will be capitalized and amortized over the expected life of the product, subject to periodic review for impairment.

Regulatory or publication achievements related to other licensed indications under study, including lung, ovarian and prostate cancers, will trigger further milestone payments to American BioScience. Such payments generally total \$17.5 million per agreed indication. As with the indication of breast cancer, those payments earned prior to FDA approval for each indication will be expensed, while amounts earned upon FDA approval of those indications will be capitalized and amortized over the expected life of the product. We have the option not to make one or more of the milestone payments tied to certain indications under study if sales of the product do not meet specified levels.

Upon achievement of major annual one-time ABRAXANE™ sales milestones, we are required to make additional payments which, in the aggregate, could total \$110.0 million should annual ABRAXANE™ sales exceed \$1.0 billion. The first sales milestone payment of \$10.0 million would be triggered upon achievement of annual calendar year ABRAXANE™ sales in excess of \$200.0 million and the second sales milestone of \$20.0 million upon the achievement of annual calendar year sales in excess of \$400.0 million. Any future sales-based milestone payments will be expensed in the period in which the sales milestone is achieved.

Under the license agreement, profit on our sales of ABRAXANE™ North America will be shared equally between American BioScience and us. The license agreement defines profit as ABRAXANE™ net sales less cost of goods sold, selling expenses (including pre-launch production and other expenses which we have expensed as incurred, but which will be charged against first profit under the agreement) and an allocation of related general and administrative expenses. We will expense American BioScience's share of any profit earned in our statements of income as an element of cost of sales. Any costs and expenses related to product recalls and product liability claims generally will be split equally between American BioScience and us and expensed as incurred. Pursuant to an agreement that we have with American BioScience, certain costs of any unsaleable ramp-up inventory of ABRAXANE™ that was manufactured in preparation for its launch will be shared equally between us and American BioScience.

In November 2001, along with the license agreement for ABRAXANE™, we also entered into a manufacturing agreement with American BioScience under which we agreed to manufacture ABRAXANE™ for American BioScience and its licensees for sales outside North America. Under this agreement, we have the right to manufacture ABRAXANE™ worldwide. For sales outside of our licensed territories, we will charge American BioScience and its licensees a customary margin on our manufacturing costs based on whether the product will be used for clinical trials or commercial sale. The initial term of this agreement is ten years and may be extended for successive two-year terms by American BioScience.

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### Loan to American BioScience

Prior to our 2001 licensing of ABRAXANE™, we made loans to American BioScience, our majority shareholder, to support development of ABRAXANE™. Subsequent to formalization of the license and manufacturing agreements in November 2001, we received a demand promissory note, which replaced prior notes, from American BioScience for the outstanding loan balance, or Demand Note. The Demand Note is capped at \$23.0 million and the terms of our September 2004 credit facility cap the note at such amount. The Demand Note bears interest at a rate equal to the rate of interest on our credit facility, which was 4.75% at December 31, 2004. American BioScience is required to repay any amounts outstanding under the Demand Note by the earlier of November 20, 2006 or our cumulative payment of \$75.0 million of profit on ABRAXANE™ to American BioScience under the license agreement. As security for American BioScience's obligations under the Demand Note, American BioScience pledged and granted to us a security interest in shares of our common stock held by American BioScience having a fair market value equal to 120% of the balance of the Demand Note.

American Pharmaceutical Partners charges incurred on American BioScience's behalf related to labor and other costs directly associated with ABRAXANE™ product development, income taxes, interest and an agreed allocation of administrative costs to the American BioScience loan account. A summary of activity in the amounts due from American BioScience, which is classified as a reduction of stockholders equity in the accompanying consolidated balance sheets, follows:

	Year Ended December 31,	
	2004	2003
	(in thousands)	
Balance at beginning of year	\$21,132	\$22,567
Payments on behalf of American BioScience:		
New product development	421	1,229
Interest charged to American BioScience	1,097	1,221
Other	(510)	85
Reductions in lieu of income tax liability	(537)	(2,252)
Repayments by American BioScience	—	(1,718)
	<u>\$21,603</u>	<u>\$21,132</u>

#### 4. Accrued Liabilities

Accrued liabilities consist of the following at:

	December 31,	
	2004	2003
	(in thousands)	
Sales and marketing	\$15,133	\$ 8,932
Payroll and employee benefits	6,893	7,785
Legal and insurance	1,976	6,383
Accrued income taxes	10,458	4,498
Other	1,102	1,522
	<u>\$35,562</u>	<u>\$29,120</u>

#### 5. Credit Facilities and Debt Extinguishment

In September 2004, we entered into a \$100 million three-year unsecured revolving credit and letter of credit facility. The new credit facility may be extended to \$150 million at our request.

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This credit facility replaced the prior \$50 million senior secured revolving credit facility which was put in place in December 2001. As a result of our early termination of the prior credit facility, we recorded a non-recurring, non-cash pretax charge of approximately \$2.0 million in the 2004 third quarter to write-off unamortized debt acquisition costs related to the prior facility. We had never drawn on the prior facility. Debt acquisition fees of approximately \$0.4 million for the new facility are being amortized over its three-year term.

Interest rates under the new credit facility vary depending on the type of loan made and our leverage ratio. The interest rate for Base Rate Loans and letters of credit is the greater of the prime rate charged by the lead bank, or the federal funds rate plus 0.5%, less an "Applicable Margin" ranging from minus 50 basis points to zero, depending on our leverage ratio. At December 31, 2004, the interest rate for Base Rate Loans under the credit facility was 4.75%. The credit facility limits the amount of and assesses a 0.125% fee on the face amount of outstanding letters of credit. With respect to the capital stock held by American BioScience, the credit facility prohibits us from declaring or paying any cash dividends or making any other such cash distributions. Additionally, the terms of our September 2004 credit facility limit the principal amount of the demand note received from American BioScience to \$23 million, among various other covenants and restrictions. There was no outstanding balance or letters of credit under the new credit facility, and we were in compliance with all covenants, at December 31, 2004.

No interest expense was capitalized during the years ended December 31, 2004, 2003 and 2001.

## 6. Leases and Commitments

We have entered into various operating lease agreements for warehouses, office space, automobiles, communications, information technology equipment and software, and office equipment. Rental expense amounted to \$3.0 million, \$2.0 million and \$2.2 million for the years ended December 31, 2004, 2003, and 2002, respectively.

As of December 31, 2004, future annual minimum lease payments related to non-cancelable operating leases are as follows:

<u>Year</u>	<u>Amount</u>
	(in thousands)
2005	\$ 2,519
2006	2,490
2007	1,712
2008	745
2009	727
Thereafter	4,404
	<u>\$ 12,597</u>

## 7. Employee Benefit Plan

We sponsor a 401(k) defined-contribution plan, or 401(k) Plan, covering substantially all eligible employees. Employee contributions to the 401(k) Plan are voluntary. In January 2005, we adopted an enhanced 401(k) plan defined-contribution plan to replace the previous plan. Under the new plan, we contribute a qualified non-elective contribution in an amount equal to 3% of all eligible employee's compensation, regardless of participation in the plan. Such employer contributions vest immediately. Employee contributions to the plan are voluntary and the plan covers all eligible employees. Participants' contributions are limited to their annual tax deferred contribution limit as allowed by the Internal Revenue Service. Our total matching contributions to the 401(k) Plan were \$1.6 million, \$1.1 million and \$1.0 million for the years ended December 31, 2004, 2003 and 2002, respectively. We may contribute additional amounts to the 401(k) Plan at our discretion. Discretionary

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employer contributions vest over a period of six years. We have never made a discretionary contribution to the 401(k) Plan. As of December 31, 2004, 142,359 common shares were reserved for issuance under our 401(k) Plan.

### **8. Employee Stock Purchase Plan**

In December 2002, our Board of Directors adopted the 2002 Employee Stock Purchase Plan, or ESPP. Under the ESPP, eligible employees may contribute up to 10% of their base earnings toward the semi-annual purchase of our common stock. The employees purchase price is the lesser of 85% of the fair market value of the stock on the first business day of the offer period or 85% of the fair market value of the stock on the last business day of the semi-annual purchase period. Employees can purchase no more than 625 shares of our common stock within any given purchase period. No compensation expense is recorded in connection with the shares issued from the ESPP. An aggregate of 6,881,308 shares of our common stock were reserved for issuance under the ESPP at December 31, 2004. The ESPP provides for annual increases in the number of shares of our common stock issuable under the ESPP equal to the lesser of: a) 3,000,000 shares, b) a number of shares equal to 2% of the total number of shares outstanding or c) a number of shares as determined by our Board of Directors. In 2004, 237,730 shares were issued under the ESPP for an aggregate purchase price of \$2.3 million. The weighted average fair values of the purchase rights granted in 2004 and 2003 were \$3.50 and \$2.71, respectively, and were issued at a weighted average price of \$9.77 and \$7.11, respectively. Of the 1,450 employees eligible to participate, 871 were participants in the ESPP at December 31, 2004.

### **9. Stockholders' Equity**

#### *Initial Public Offering*

In December 2001, we completed our initial public offering of 13,500,000 shares of common stock at a public offering price of \$10.67 per share. The offering generated total proceeds of \$144.0 million and, after \$13.0 million in underwriting discounts and commissions, net proceeds of \$131.0 million. In January 2002, the underwriters for our initial public offering exercised in full their option to purchase an additional 2,025,000 shares of our common stock at the initial public offering price of \$10.67 per share to cover over-allotments. As a result of this exercise, we received proceeds of \$20.1 million, net of underwriting discounts and commissions of \$1.5 million.

#### *Common Stock Voting Rights*

The holders of our common stock are entitled to one vote for each share held of record upon such matters and in such manner as may be provided by law.

#### *Preferred Stock*

We are authorized to issue up to 6,000,000 shares of preferred stock that is not designated as a particular class. Our Board of Directors may authorize and cause the issuance of the undesignated preferred stock in one or more series, determine the powers, preferences and rights and the qualifications, limitations or restrictions granted to or imposed upon any wholly unissued series of undesignated preferred stock and to fix the number of shares constituting any series and the designation of the series, without any further vote or action by our stockholders.

#### *Dividends*

We have never paid a dividend on any class of stock and have no current intention of paying cash dividends in the future. In the event that we liquidate, dissolve or wind-up, the holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and liquidation preferences of any outstanding shares of preferred stock. Holders of our common stock have no preemptive rights or rights to convert their common stock into any other securities.

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### *Registration Rights*

The holders of 56,861,089 shares of our common stock, which includes shares held by American BioScience, are entitled to registration rights with respect to their shares. These holders may require us to include their shares in our registration statements and may require us to register all, or a portion of their shares. Upon registration, these shares would be freely tradable in the public market without restriction.

Generally, all expenses in effecting these registration statements, with the exception of underwriting discounts and selling commissions, are borne by us. These registration rights are subject to some conditions and limitations, among them the right of the underwriters of an offering to limit the number of shares included in a registration. We agreed to indemnify the holders of these registration rights, and each selling holder has agreed to indemnify us, against liabilities under the Securities Act, the Securities Exchange Act or other applicable federal or state law.

### *Treasury Stock*

Pursuant to a December 2002 authorization by our Board of Directors, we repurchased 1,596,081 of our shares in the 2003 first quarter for \$20.0 million. Additionally, in 2002, we repurchased all 4,371,891 shares of our common stock held by Premier Purchasing Partners LP, for \$30.3 million in cash, including transaction costs and repurchased 678,426 shares of our common stock owned by Biotechnology Development Fund, L.P. for \$6.0 million in cash, both pursuant to a stock repurchase program adopted by our Board of Directors on July 26, 2002. These repurchases were funded using our internal cash resources and are being held as treasury shares to be used for general corporate purposes. In aggregate, the 6,646,398 common shares held as treasury stock at December 31, 2004 have a cost basis of \$8.47 per share.

## **10. Stock Options**

### *1997 Stock Option Plan*

During 1998, our Board of Directors authorized the 1997 Stock Option Plan, or the 1997 Plan. Under the 1997 Plan, options to purchase shares of our common stock may be granted to certain employees and directors with an exercise price equal to the estimated fair market value of our common stock on the date of grant. The stock options have a term of 10 years with a vesting period of four years. In accordance with the terms of the 1997 Plan, options granted to employees on or before December 1, 1999 vested immediately upon completion of our initial public offering. No further options will be granted under the 1997 Plan.

### *2001 Stock Incentive Plan*

In December 2001, our Board of Directors authorized the 2001 Stock Incentive Plan, or the 2001 Plan. The 2001 Plan provides for the grant of incentive stock options and restricted stock to employees, including officers and employee directors, non-qualified stock options to employees, directors and consultants, and restricted stock and other types of awards. At December 31, 2004, there were 12,795,610 options available for grant, and 17,765,747 common shares reserved for the exercise of stock options under the 2001 Plan. The number of shares reserved for issuance increases annually on the first day of each fiscal year by an amount equal to the lesser of a) 6,000,000 shares, b) 5% of the total number of shares outstanding as of that date, or c) a number of shares as determined by our Board of Directors.

Our Board of Directors, or a committee designated by the Board of Directors, administers the 2001 Plan and has authority to determine the terms and conditions of awards, including the types of awards, the number of shares subject to each award, the vesting schedule of the awards and the selection of grantees.

The exercise price of all options granted under the 2001 Plan will be determined by our Board of Directors or a committee designated by our Board of Directors, but in no event will this price be less than the fair market value of our common stock on the date of grant, unless otherwise determined by the Board of Directors with respect to non-qualified stock options.

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### 2001 Non-Employee Director Stock Option Program

The 2001 Non-Employee Director Stock Option Program, or the 2001 Program, was adopted as part, and is subject to the terms and conditions, of the 2001 Plan. The 2001 Program establishes an automatic option grant program for the grant of awards to non-employee directors.

The 2001 Program is administered by our Board of Directors, or a committee designated by the Board of Directors. Also, the Board of Directors, or a committee designated by the Board of Directors, determines the terms and conditions of awards, and construe and interpret the terms of the program and awards granted under the program. Non-employee directors may also be granted additional incentive awards, subject to the discretion of the Board of Directors, or a committee designated by the Board of Directors.

#### Restricted Stock

On June 4, 2004, 10,000 restricted common shares, having a market value on that date of \$34.03 per share, were issued under the 2001 Stock Option Plan. One-quarter of the shares vest five years from date of grant, one-quarter vest have a vesting period of six years, and the remainder have a vesting period of seven years, subject to active employment. On November 16, 2004, 50,000 restricted common shares, having a market value on that date of \$28.38 per share, were issued under the 2001 Stock Option Plan. The shares vest over the earlier of five years from grant date or the achievement of a specific financial objective, subject to active employment. On February 25, 2003, 42,000 restricted common shares, having a market value on that date of \$14.69 per share, were issued under the 2001 Stock Option Plan. Three-quarters of the shares vest three years from date of grant with the remainder vesting four years from the date of grant, subject to active employment. Compensation expense related to restricted stock grants is based upon the market price on date of grant and charged to earnings on a straight-line basis over the vesting periods.

#### Stock Option Activity

Stock option activity is as follows:

	Options Outstanding		Exercisable Options	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
Outstanding at January 1, 2002	5,181,658	\$ 3.53		
Granted	600,450	10.12		
Exercised	(874,776)	2.19		
Forfeited	(317,354)	7.33		
Outstanding at December 31, 2002	4,589,978	4.43	2,395,383	\$ 2.81
Granted	1,126,150	19.17		
Exercised	(973,746)	3.18		
Forfeited	(243,877)	10.81		
Outstanding at December 31, 2003	4,498,505	8.05	2,136,269	\$ 3.55
Granted	1,094,600	32.56		
Exercised	(461,983)	4.81		
Forfeited	(160,985)	23.75		
Outstanding at December 31, 2004	4,970,137	\$ 13.24	2,625,886	\$ 5.62

The weighted average fair value of options granted was \$19.56, \$11.34 and \$6.32 for the years ended December 31, 2004, 2003 and 2002, respectively, as calculated using the Black-Scholes option pricing model.

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The following table summarizes information about all stock options outstanding as of December 31, 2004:

Exercise Price Ranges	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price
\$ 2.00—\$ 5.00	2,206,528	4.2	\$ 3.02	1,879,285	\$ 2.84
\$ 5.01—\$10.00	504,889	6.4	7.86	297,634	7.70
\$10.01—\$15.00	694,969	7.7	12.07	321,859	11.93
\$15.01—\$20.00	152,655	8.3	15.95	27,047	15.59
\$20.01—\$25.00	227,159	9.0	22.35	37,066	22.65
\$25.01—\$30.00	551,318	9.3	27.42	26,720	28.45
\$30.01—\$35.00	233,644	8.2	32.24	21,800	32.13
\$35.01—\$40.00	162,975	9.3	36.83	14,475	37.88
\$40.01—\$45.00	53,000	8.9	42.43	—	—
\$45.01—\$50.00	183,000	9.2	45.90	—	—
	<u>4,970,137</u>	<u>6.4</u>	<u>\$ 13.24</u>	<u>2,625,886</u>	<u>\$ 5.62</u>

### Stock-Based Compensation

Our stock-based compensation expense results from the issuance of stock based compensation which was either performance-based or, prior to the date of our initial public offering, for which the exercise price was less than the estimated fair value of common stock on the grant date. In connection with such stock-based compensation we determine the amount of related compensation recognized to be the difference between the exercise price and the fair value of our common stock at that date. Stock-based compensation is deferred and classified as a reduction of stockholders' equity and is amortized to expense primarily on an accelerated basis using the graded vesting method over the applicable vesting period. Such expense amounted to \$1.1 million, \$1.2 million and \$2.3 million for the years ended December 31, 2004, 2003 and 2002, respectively.

## 11. Income Taxes

Deferred tax assets and liabilities consist of the following:

	December 31,	
	2004	2003
	(in thousands)	
Deferred tax assets:		
Inventory	\$ 4,385	\$ 1,900
Amortization of stock-based compensation	1,638	1,420
Customer discounts	1,339	914
Other accruals and reserves	7,288	5,276
Total deferred tax assets	<u>14,650</u>	<u>9,510</u>
Deferred tax liabilities:		
Organization costs	(383)	(383)
Depreciation	(4,275)	(3,080)
Other accruals and reserves	—	(143)
Total deferred tax liabilities	<u>(4,658)</u>	<u>(3,606)</u>
Net deferred tax asset	<u>\$ 9,992</u>	<u>\$ 5,904</u>

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The provisions for income tax consists of the following:

	Year ended December 31,		
	2004	2003	2002
	(in thousands)		
Current:			
Federal	\$29,949	\$36,085	\$29,877
State	4,388	8,073	6,299
Foreign	1,891	1,219	205
Total current	36,228	45,377	36,381
Deferred:			
Federal	(3,373)	1,114	(2,457)
State	(715)	884	(824)
Total deferred	(4,088)	1,998	(3,281)
Total provision for income taxes	\$32,140	\$47,375	\$33,100

The amount of our allocated current liability for income taxes is accounted for through the due from American BioScience account and was \$0.8 million and \$2.3 million for the years ended December 31, 2004 and 2003, respectively. Since our initial public offering, we have not been included in American BioScience's consolidated federal income tax return.

A reconciliation of the federal statutory rate to the Company's effective tax rate is as follows:

	Year ended December 31,		
	2004	2003	2002
Tax provision at statutory federal rate	35.0%	35.0%	35.0%
State income taxes, net of federal income tax benefit	4.8	4.8	5.2
Permanent items	—	0.2	—
Tax rate change in state deferred taxes	—	0.1	—
Non-includible income	(0.9)	(0.3)	2.1
Tax credits	(2.7)	—	—
Effective tax rate	36.2%	39.8%	42.3%

## 12. Acquisition of Assets

On July 28, 2004, we acquired certain assets, including a 25,000 square foot manufacturing facility and certain injectable oncology product rights for a purchase price of approximately \$11 million in cash, subject to final adjustment. Located in Barbengo, Switzerland, the FDA approved facility uses Isolator Technology which is particularly suitable for the manufacture of oncolytic products, including daunorubicin, methotrexate, and leucovorin calcium, for our U.S. operations. Additionally, we acquired eight FDA approved ANDAs covering 15 product codes and one ANDA pending with the U.S. FDA in the transaction which also included a number of generic injectable oncology products currently marketed in Europe and South America and a number of Marketing Authorization Applications, or MAAs, currently approved or pending with the European Agency for the Evaluation of Medicinal Products.

## 13. Regulatory Matters

The Company is subject to regulatory oversight by the United States Food and Drug Administration and other regulatory authorities with respect to the development and manufacturing of its products. Failure to comply with regulatory requirements can have a significant effect on our business and operations. Management has designed and operates a system of controls to attempt to ensure compliance with regulatory requirements.

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**14. Litigation**

In October and November of 2003, several purported federal securities class action lawsuits were filed against us in the United States District Court for the Northern District of Illinois. All of the class action lawsuits were consolidated in March 2004. In February 2005, the consolidated federal class action lawsuit against us was voluntarily dismissed by the plaintiffs with prejudice.

Additionally, in December 2003 a purported shareholder derivative action was filed in the Circuit Court of Cook County, Illinois, Chancery Division against each member of our Board of Directors and one non-director executive officer alleging essentially the same claims as were alleged in the federal class action lawsuit. In March 2005, the shareholder derivative action was voluntarily dismissed by the plaintiffs without prejudice.

We are from time to time subject to claims and litigation arising in ordinary courses of business. These claims have included assertions that our products infringe existing patents and also claims that the use of our products has caused personal injuries. We intend to defend vigorously any such litigation that may arise under all defenses that would be available to us. In the opinion of management, the ultimate outcome of proceedings of which management is aware, even if adverse to us, will not have a material adverse effect on our consolidated financial position or results of operations.

**15. Net Sales by Product**

Net sales by product line is as follows:

	Year Ended December 31,		
	2004	2003	2002
(in thousands)			
Critical care	\$ 178,242	\$ 169,849	\$ 135,370
Anti-infective	125,052	95,581	74,082
Oncology	95,866	81,049	61,204
Contract manufacturing	5,739	4,088	5,840
Other	111	748	978
	<u>\$ 405,010</u>	<u>\$ 351,315</u>	<u>\$ 277,474</u>

**16. Unaudited Quarterly Financial Data**

Selected quarterly data for 2004 and 2003 is as follows:

	2004			
	First	Second	Third	Fourth
(in thousands, except per share data)				
Net sales	\$ 89,178	\$ 97,664	\$ 95,614	\$ 122,554
Gross margin	\$ 44,387	\$ 53,141	\$ 51,699	\$ 66,482
Net income	\$ 11,769	\$ 9,245	\$ 13,813	\$ 21,866
Income per common share:				
Basic	\$ 0.17	\$ 0.13	\$ 0.20	\$ 0.31
Diluted	\$ 0.16	\$ 0.13	\$ 0.19	\$ 0.30
	2003			
	First	Second	Third	Fourth
Net sales	\$ 81,345	\$ 90,416	\$ 90,354	\$ 89,200
Gross margin	\$ 46,160	\$ 50,626	\$ 48,537	\$ 46,054
Net income	\$ 17,055	\$ 19,818	\$ 18,290	\$ 16,530
Income per common share:				
Basic	\$ 0.24	\$ 0.29	\$ 0.26	\$ 0.24
Diluted	\$ 0.23	\$ 0.27	\$ 0.25	\$ 0.23

Sales and gross margin in the fourth quarter of 2004 benefited from recent product launches, primarily carboplatin, and continued strength in the anti-infective and oncology product categories.

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

None.

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

**(a) Evaluation of disclosure controls and procedures.**

Based on their evaluation of our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934) as of a date within 90 days of the filing date of this Annual Report on Form 10-K, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and are operating in an effective manner.

**(b) Internal control over financial reporting**

Management's Report on Internal Control over Financial Reporting and our Independent Registered Public Accounting Firm's Attestation Report are included in Item 8.

**(c) Changes in internal controls.**

There were no significant changes in our internal controls or in other factors that could significantly affect these controls during the quarter ended December 31, 2004.

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

On November 19, 2004, after a review of competitive data and in connection with his new role as our Executive Chairman, our board of directors approved an increase in the base salary of Patrick Soon-Shiong from \$383,500 to \$600,000 per annum effective as of such date.

**PART III**

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

The information regarding our directors is incorporated by reference from the information contained under the caption "Election of Directors" in our 2005 Proxy Statement for the 2005 Annual Meeting of Stockholders. Further, information regarding Section 16 reporting compliance is incorporated by reference from information contained under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in our 2005 Proxy Statement.

**Item 11. *Executive Compensation***

The information regarding executive compensation is incorporated by reference to the information under the captions "Summary Compensation Table," "Option Grants in Last Fiscal Year," and "Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values" in our 2005 Proxy Statement.

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

The information required by this Item is set forth in our 2005 Proxy Statement, under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information," which information is hereby incorporated herein by reference.

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**Item 13. *Certain Relationships and Related Transactions***

The information about certain relationships and related transactions is set forth in our 2005 Proxy Statement, under the caption “Compensation Committee Interlocks and Insider Participation,” which information is hereby incorporated herein by reference.

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

Incorporated herein by reference is the material under the headings “Audit Fees and Non–Audit Fees” and “Policy on Audit Committee Pre–Approval of Audit and Permissible Non–Audit Services of the Independent Auditor” in our 2005 Proxy Statement.

**PART IV**

**Item 15. *Exhibits, Financial Statement Schedule and Reports on Form 8–K***

**a. (1) Financial Statements**

The following consolidated financial statements of American Pharmaceutical Partners, Inc. are included in Part II, Item 8 of this Report:

- Management’s Report on Internal Control over Financial Reporting
- Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting
- Report of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets at December 31, 2004 and 2003
- Consolidated Statements of Income for the Years Ended December 31, 2004, 2003 and 2002
- Consolidated Statements of Stockholders’ Equity for the Years Ended December 31, 2004, 2003 and 2002
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2004, 2003 and 2002
- Notes to Consolidated Financial Statements

**(2) Financial Statement Schedule**

The following consolidated financial statement schedule of American Pharmaceutical Partners, Inc. is filed as part of this Report:

- Schedule II. Valuation and Qualifying Accounts and Reserves

All other schedules are omitted because the required information is not present or is not present in amounts sufficient to require submission of the schedule or because the information required is given in the consolidated financial statements or the notes thereto.

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### (3) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant
3.2(1)	Bylaws of the Registrant
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2(2)	Specimen Stock Certificate of the Registrant
4.3(3)	First Amended Registration Rights Agreement, dated as of June 1, 1998, between the Registrant and certain holders of the Registrant's capital stock
10.1(4)	Form of Indemnification Agreement between the Registrant and each of its executive officers and directors
10.2(3)	1997 Stock Option Plan
10.3(3)	2001 Stock Incentive Plan, including forms of agreements thereunder
10.4(3)	2001 Employee Stock Purchase Plan, including forms of agreements thereunder
10.5(3)	Office Lease Agreement dated January 29, 1999 between the Registrant and Woodfield Executive Center, Inc.
10.6(3)	Lease Agreement dated December 4, 2000, between the Registrant and AMB Property II, L.P.
10.7(4)	Tax Sharing and Indemnification Agreement dated July 25, 2001, between the Registrant and American BioScience
10.8(4)	Agreement, dated as of July 25, 2001, between the Registrant and American BioScience
10.9(4)	Agreement, dated as of July 25, 2001, between the Registrant and American BioScience
10.10(2)	License Agreement, dated as of November 20, 2001, between the Registrant and American BioScience
10.11(2)	Manufacturing Agreement, dated as of November 20, 2001, between the Registrant and American BioScience
10.12(4)	Compensation Protection Agreement, dated as of November 20, 2001, between the Registrant and Derek J. Brown
10.13(4)	Compensation Protection Agreement, dated as of November 20, 2001, between the Registrant and Jeffrey M. Yordon
10.14(4)	Compensation Protection Agreement, dated as of November 20, 2001, between the Registrant and Jack C. Silhavy
10.15(4)	Credit Agreement, dated as of December 14, 2001, between the Registrant, Canadian Imperial Bank Commerce, Bank of America, N.A., UBS Warburg LLC, and the several lenders from time to time parties thereto
10.16(7)	Compensation Protection Agreement, dated as of August 19, 2002, between the Registrant and Nicole S. Williams
10.18(7)	Lease Agreement between Manufacturers Life Insurance Company (U.S.A.) and the Registrant for 1501 E. Woodfield Road, Suite 300 East in Schaumburg, Illinois, known as Schaumburg Corporate Center
10.19(7)	Agreement dated as of March 11, 2004, between the Registrant and American BioScience
10.20(8)	Credit Agreement dated September 2, 2004 among the Registrant, Fifth Third Bank, Wachovia Bank, and various lenders
10.21	Employment Agreement dated November 15, 2004 between the Registrant and Alan Heller

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10.22(9)	Description of the 2005 Corporate Bonus Plan
10.23(9)	2005 Base Salaries for Named Executive Officers
14.1(7)	Code of Business Conduct of the Registrant dated February 2004
21.1(1)	List of Subsidiaries of the Registrant
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as added by Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as added by Section 906 of the Sarbanes-Oxley Act of 2002.

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- (1) Incorporated by reference to Registrant's Registration Statement filed on Form S-1/A, file number 333-70900, filed with the Securities and Exchange Commission on December 11, 2001.
  - (2) Incorporated by reference to Registrant's Registration Statement filed on Form S-1/A, file number 333-70900, filed with the Securities and Exchange Commission on December 13, 2001.
  - (3) Incorporated by reference to Registrant's Registration Statement filed on Form S-1, file number 333-70900, filed with the Securities and Exchange Commission on October 3, 2001.
  - (4) Incorporated by reference to Registrant's Registration Statement filed on Form S-1/A, file number 333-70900, filed with the Securities and Exchange Commission on November 20, 2001.
  - (5) Incorporated by reference to the Registrant's report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2002.
  - (6) Incorporated by reference to the Registrant's report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2002.
  - (7) Incorporated by reference to the Registrant's report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2004.
  - (8) Incorporated by reference to the Registrant's report on Form 8-K filed with the Securities and Exchange Commission on September 9, 2004.
  - (9) Incorporated by reference to the Registrant's report on Form 8-K filed with the Securities and Exchange Commission on February 23, 2005.
- \* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission.



**FINANCIAL SCHEDULE**  
**SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS AND RESERVES**

A	B	C	D	E
Year Ended December 31,	Balance at Beginning of Period	(1) Additions	(2) Deductions	Balance at End of Period
(in thousands)				
Allowance for doubtful accounts:				
2004	\$510	\$ 122	\$ —	\$ 632
2003	\$801	\$ (291)	\$ —	\$ 510
2002	\$400	\$ 401	\$ —	\$ 801

## EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement") is entered into as of November 15, 2004 between AMERICAN PHARMACEUTICAL PARTNERS, INC., a Delaware corporation (the "Company") and ALAN L. HELLER (the "Executive").

RECITAL

The Company desires to employ the Executive, and the Executive desires to be so employed by the Company, on the terms and subject to the conditions set forth in this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the premises and the mutual promises set forth in this Agreement, the Company and the Executive hereby agree as follows:

1. Definitions. Unless otherwise defined herein, the capitalized terms defined in Exhibit A shall have the meanings therein specified for all purposes of this Agreement.

2. Employment.

(a) Subject to the terms and conditions contained herein, the Company hereby agrees to employ the Executive, and the Executive accepts such employment, from November 16, 2004 (the "Effective Date") until the Termination Date.

(b) During the Executive's employment under this Agreement, the Executive shall render services to the Company in the position of President and Chief Executive Officer. The Executive shall also be appointed as a member of the Board as promptly as practicable following the Company's 2004 annual stockholder meeting. The Executive shall perform such duties and responsibilities as are normally related to such positions and any additional duties now or hereafter assigned to Executive by the Board.

(c) In performing his services hereunder, the Executive shall abide by the rules, regulations, and practices as adopted or modified from time to time in the Company's sole discretion.

(d) The Executive will devote his entire business time, energy, attention and skill to the services of the Company and to the promotion of its interests. So long as the Executive is employed by the Company, the Executive shall not, without the written consent of the Company:

(i) engage in any other activity for compensation, profit or other pecuniary advantage, whether received during or after the term of this Agreement;

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(ii) render or perform services of a business, professional, or commercial nature other than to or for the Company, either alone or as an employee, consultant, director, officer, or partner of another business entity (including serving on boards of directors), whether or not for compensation; or

(iii) plan or otherwise take any preliminary steps, either alone or in concert with others, to establish or engage in any business or activity that would compete with the current or proposed business of the Company;

provided, that it shall not be a violation of this Agreement for the Executive to (i) serve on civic or charitable boards or committees, (ii) deliver lectures or fulfill speaking engagements, (iii) manage personal investments and (iv) perform such other activities as the Board may approve, so long as such activities do not interfere materially with the performance of the Executive's responsibilities as the President and Chief Executive Officer of the Company.

(e) Prior to or concurrently with the execution of this Agreement, the Executive has executed an Executive Proprietary Information, Trade Secret and Confidentiality Agreement (the "Confidentiality Agreement").

3. Location of Employment. The Executive's principal place of employment shall be at the principal executive office of the Company (currently located in Schaumburg, Illinois); provided, that at the reasonable direction of the Board or the Chairman of the Board, the Executive may, from time to time, be required to travel to various domestic and foreign locations for purposes consistent with his duties hereunder.

4. Compensation.

(a) In exchange for full performance of the Executive's obligations and duties under this Agreement, the Company shall pay the Executive a salary at the rate of Six Hundred Thousand Dollars (\$600,000) per year ("Base Salary"). The Base Salary shall be paid in accordance with the Company's regularly established payroll practice. The Base Salary will be reviewed from time to time in accordance with the established procedures of the Company for adjusting salaries for similarly situated employees and may be adjusted in the sole discretion of the Board or the Compensation Committee.

(b) The Base Salary hereof is a gross amount, and the Company shall be required to withhold from such amount deductions with respect to Federal, state and local taxes, FICA, unemployment compensation taxes and similar taxes, assessments or withholding requirements.

(c) During the Executive's employment under this Agreement, the Executive shall also be reimbursed by the Company for reasonable business expenses actually incurred or paid by the Executive, consistent with the policies established by the Board, in rendering to the Company the services provided for in this Agreement.

(d) The Executive shall be entitled to vacation and sick leave on terms equivalent to those of other executive officers of the Company.

(e) The Executive shall be entitled to participate in all benefit plans (including but not limited to any medical, dental, life insurance, retirement and disability plans) which shall be available from time to time to the executive officers of the Company generally; provided, however, that the Executive shall have no right under this Agreement to participate in any stock option, stock purchase or other plan relating to shares of capital stock of the Company or its affiliates (except as otherwise expressly provided in subsections (f) and (g) below). The Executive acknowledges and agrees that the Board may, in its discretion, terminate at any time or modify from time to time any such benefit plans.

(f) On the Effective Date, the Executive shall be granted:

(i) An option to purchase 150,000 shares of the Common Stock, which option (A) shall have an exercise price equal to the trading price of the Common Stock as of the Effective Date, (B) shall vest in annual installments of 37,500 over a four-year period, (C) shall be evidenced by the Company's standard form of stock option agreement for its executive officers and shall otherwise be subject to the terms and conditions of the Stock Incentive Plan (except as modified by this Agreement).

(ii) A restricted stock award of 50,000 shares of the Company's Common Stock, which shares (A) shall vest in their entirety on the earlier to occur of (x) the fifth anniversary of the Effective Date or (y) the date it is determined that the Company achieved an annual EBITDA of at least \$500 million in any fiscal year, and (B) shall be evidenced by the Company's standard form of restricted stock option agreement and shall otherwise be subject to the terms and conditions of the Stock Incentive Plan (except as modified by this Agreement).

(g) In addition to the grants described in subsection (f) above, commencing in 2006 (for stock option awards determined by the Board with respect to the 2005 fiscal year), the Executive shall be entitled to receive annual grants of stock options (at the same time such grants are made to the other executive officers of the Company), in such amounts and subject to such terms as may be determined in the sole discretion of the Board or the Company's Compensation Committee.

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(h) The Executive shall be entitled to receive an annual cash bonus in such amount, and subject to such performance targets and other factors, as may be determined the sole discretion of the Board or the Company's Compensation Committee. The target bonus amounts and performance targets for the Executive shall be established at the same time such amounts and targets are established for the other executive officers of the Company, and any bonuses earned shall be paid at the same time as bonuses for other executive officers. The Executive acknowledges that under the Company's current bonus policy, (i) in early 2005, the Board will determine the financial targets for 2005 for bonus purposes, (ii) the Executive will be eligible to receive a bonus equal to 80% of the Base Salary if such financial targets are met and (iii) the actual amount of bonus will be between 0% and 120% of Base Salary, based upon actual financial results achieved in 2005.

(i) Other than as expressly set forth in this Section 3, the Executive shall not receive any other compensation or benefits except to the extent provided by the Board.

5. Term. The Executive's employment hereunder shall commence on the Effective Date and shall continue in effect until terminated pursuant to Section 6 below.

6. Termination. The Executive's employment hereunder may be terminated as follows:

(a) **Death**. The employment of the Executive under this Agreement shall terminate on the date of the Executive's death.

(b) **Disability**. The employment of the Executive under this Agreement may be terminated by the Company immediately upon giving the Executive notice if the Executive becomes Disabled.

(c) **Termination With Cause**: The employment of the Executive under this Agreement may be terminated by the Company immediately upon giving the Executive notice upon the occurrence of Cause.

(d) **Termination Without Cause**. In addition to the circumstances described in subsection (c) above, the Company may terminate the Executive's employment at any time (immediately upon giving notice to the Executive) for any reason or no reason, with or without Cause or prior notice.

**(e) Voluntary Termination.**

(i) The employment of the Executive under this Agreement shall terminate upon receipt by the Board of a written notice of resignation signed by the Executive or, if no notice is given, on the date on which the Executive voluntarily terminates his employment relationship with the Company.

(ii) Such voluntary termination shall be deemed for purposes hereof to have occurred for "Good Reason" only if (i) the Executive provides written notice to the Company within 20 days after the Executive becomes aware of the circumstances giving rise to "Good Reason", (ii) the Company fails to correct the circumstances giving rise to "Good Reason" within 30 days following receipt of such notice and (iii) the Executive resigns within 15 days following such 30-day period.

**7. Consequences of Termination.**

(a) If the employment of the Executive under this Agreement is terminated pursuant to 6(a) (Death), 6(b) (Disability), 6(c) (Termination With Cause) or 6(e)(i) (Voluntary Termination, other than for Good Reason), then (i) the Company shall pay the Executive (or, as applicable, his heirs, estate or representative) the Accrued Compensation, (ii) the Company shall provide to the Executive (or his dependents, as applicable) such benefits, if any, as may be required to be provided by the Company under the Comprehensive Omnibus Budget Reconciliation Act ("COBRA") and any disability policy of the Company applicable to the Executive, and (iii) the Executive shall not be entitled to any other compensation or benefits from the Company, under this Agreement or otherwise.

(b) If the employment of the Executive under this Agreement is terminated pursuant to Section 6(d) (Termination Without Cause) or 6(e)(ii) (Voluntary Termination for Good Reason), then the Executive shall not be entitled to any compensation or benefits from the Company, under this Agreement or otherwise, except for the following:

(i) The Company shall pay to the Executive all Accrued Compensation;

(ii) The Company shall pay the Executive, for the duration of the Severance Period, severance payments at an annual rate (pro rated over the Severance Period) equal to (i) the Base Amount plus (ii) the Bonus Amount, which amount will be payable in arrears in monthly installments. Such monthly installments will be delayed to the minimum extent necessary to meet the requirements of Internal Revenue Code Section 409A, as amplified by any applicable Internal Revenue Service or U.S. Treasury Department guidance. The Company and the Executive shall reasonably cooperate with each other to avoid the imposition of any additional taxes, interest and/or penalty to the Executive under Internal Revenue Code Section 409A;

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(iii) Provided that the Executive elects to continue his health care coverage under COBRA, the Company shall pay the premiums for such COBRA coverage until the earlier of the following: (a) the 18-month anniversary of the Termination Date or (b) the date on which the Executive becomes covered by comparable benefits under another benefits plan;

(iv) The vesting of the stock options granted to the Executive under subsection (f)(i) above shall accelerate so that such options shall have vested to the same extent as would if the Executive were terminated on the last day of the Severance Period; and

(v) The restrictions applicable to the restricted stock award granted to the Executive under subsection (f)(ii) above shall lapse as to such number of shares as equal (i) 12,500 shares, multiplied by (ii) the number of twelve-month periods elapsed between the Effective Date and the Termination Date.

provided, that the Executive shall not be entitled to receive any post-termination benefits described in clause (ii)-(v) of this subsection (b) unless, within 21 days following the Termination Date, he executes and delivers to the Company a Release of Claims in the form attached as Exhibit B hereto.

(c) The Executive agrees that all property (including, without limitation, all equipment, tangible proprietary information, documents, records, notes, contracts and computer-generated materials) furnished to or created or prepared by Executive incident to Executive's employment belongs to the Company and shall be promptly returned to the Company upon termination of the Executive's employment.

(d) Upon termination of the Executive's employment, the Executive shall be deemed to have resigned from all offices and directorships then held with the Company. Following any termination of employment, the Executive shall reasonably cooperate with the Company (i) in the winding up of pending work on behalf of the Company and the orderly transfer of work to other employees and (ii) in the defense of any action brought by any third party against the Company that relates to the Executive's employment by the Company; provided, that in each case the Company shall reimburse the executive for any out-of-pocket fees and expenses incurred by the Executive in connection with such cooperation.

#### 8. Additional Post-Termination Obligations.

(a) In the event that Executive receives severance payments pursuant to Section 7(b), the Executive agrees that for a period of two years following the

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Termination Date, the Executive will not, directly or indirectly, engage in any business activity that is or may reasonably be found to be in competition with the business of the Company and its subsidiaries as such business may exist at any time from the Effective Date through the Termination Date; provided, that nothing in this Agreement shall be deemed to prohibit Executive from owning not more than one percent (1%) of any class of publicly traded securities of a competitor.

(b) The Executive further agrees that for a period of two years following the Termination Date the Executive will not:

(i) Solicit, raid, entice or induce any employee of the Company to be employed by any competitor of the Company (except to the extent that such employee has first responded to a general advertisement or general employment search by Executive's place of employment at the time);

(ii) Solicit business for any competitor from, or transact such business for any competitor with, any person, firm or corporation which was, at any time during Executive's employment hereunder, a customer of the Company; or

(iii) Assist a competitor in taking such action.

(c) If the Executive fails to perform his obligations under this Section 8, then the Company may, in addition to any rights and remedies then available to the Company (under Section 11 hereof or otherwise), cease providing the payments and benefits described in Section 7(b) so long as such failure, if reasonably capable of being cured, is not cured by the Executive within 30 days following a written notice from the Company of such failure to perform.

#### 9. Representations.

(a) The Executive represents that he has full authority to enter into this Agreement and is not under any contractual restraint which would prohibit the Executive from satisfactorily performing his duties to the Company under this Agreement.

(b) The Executive hereby agrees to indemnify and hold harmless the Company, its officers, directors and stockholders from and against any losses, liabilities, damages or costs (including reasonable attorney's fees) arising out of a material breach of any of the representations, warranties and covenants of the Executive set forth in this Agreement. The Company hereby agrees to indemnify and hold harmless the Executive from and against any losses, liabilities, damages or costs (including reasonable attorney's fees) arising out of a material breach of any of the representations, warranties and covenants of the Company set forth in this Agreement.

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(c) The Executive acknowledges that he is free to seek advice from independent counsel with respect to this Agreement. The Executive has either obtained such advice or, after carefully reviewing this Agreement, has decided to forego such advice. The Executive is not relying on any representation or advice from the Company or any of its officers, directors, attorneys or other representatives regarding this Agreement, its content or effect.

10. Arbitration. Subject to Section 11 below, the parties acknowledge and agree to the provisions on Exhibit C hereto relating to the arbitration of disputes hereunder (subject to Section 11).

11. Equitable Relief. Notwithstanding Section 10 above, the Executive acknowledges that the Company is relying for its protection upon the existence and validity of the provisions of this Agreement, that the services to be rendered by the Executive are of a special, unique and extraordinary character, and that irreparable injury will result to the Company from any violation or continuing violation of the provisions of Section 8(b) for which damages may not be an adequate remedy. Accordingly, the Executive hereby agrees that in addition to the remedies available to the Company by law or under this Agreement, the Company shall be entitled to obtain such equitable relief as may be permitted by law in a court of competent jurisdiction including, without limitation, injunctive relief from any violation or continuing violation by the Executive of any term or provision of Section 8(b).

12. Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the internal substantive laws (and not the laws of conflicts) of the State of Illinois.

13. Entire Agreement. This Agreement (including the Exhibits hereto) constitutes the whole agreement of the parties hereto in reference to any employment of the Executive by the Company and in reference to any of the matters or things herein provided for or hereinabove discussed or mentioned in reference to such employment; all prior agreements, promises, representations and understandings relative thereto being herein merged.

14. Assignability.

(a) In the event the Company shall merge or consolidate with any other corporation, partnership or business entity, or all or substantially all of the Company's business or assets shall be transferred in any manner to any other corporation, partnership or business entity, then such successor to the Company shall thereupon succeed to, and be subject to, all rights, interests, duties and obligations of, and shall thereafter be deemed for all purposes hereof to be, the "Company" under this Agreement.

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(b) This Agreement is personal in nature and the Executive shall not, without the written consent of the Company, assign or transfer this Agreement or any rights or obligations hereunder.

(c) Except as set forth in subsection (a) above, nothing expressed or implied in this Agreement is intended or shall be construed to confer upon or give to any person, other than the parties to this Agreement, any right, remedy or claim under or by reason of this Agreement or of any term, covenant or condition of this Agreement.

15. Amendments; Waivers. This Agreement may be amended, modified, superseded, canceled, renewed or extended and the terms or covenants of this Agreement may be waived only by a written instrument executed by the parties to this Agreement or, in the case of a waiver, by the party waiving compliance. Any such written instrument must be approved by the Board to be effective as against the Company. The failure of any party at any time or times to require performance of any provision of this Agreement shall in no manner affect the right at a later time to enforce the same. No waiver by any party of the breach of any term or provision contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such breach, or a waiver of the breach of any other term or covenant contained in this Agreement.

16. Notice. All notices, requests or consents required or permitted under this Agreement shall be made in writing and shall be given to the other parties by personal delivery, registered or certified mail (with return receipt), overnight air courier (with receipt signature) or facsimile transmission (with "answerback" confirmation of transmission), sent to such party's addresses or teletype numbers as are set forth below such party's signatures to this Agreement, or such other addresses or teletype numbers of which the parties have given notice pursuant to this Section 16. Each such notice, request or consent shall be deemed effective upon the date of actual receipt, receipt signature or confirmation of transmission, as applicable (or if given by registered or certified mail, upon the earlier of (i) actual receipt or (ii) three days after deposit thereof in the United States mail).

17. Severability. Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

18. Survival. The representations and agreements of the parties set forth in Sections 7, 8, 9, 10, 11 and 19 of this Agreement shall survive the expiration or termination of this Agreement (irrespective of the reason for such expiration or termination).

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19. Attorneys' Fees. If any party to this Agreement seeks to enforce his or its rights under this Agreement, the prevailing party or parties shall be entitled to recover reasonable fees, costs and expenses incurred in connection therewith including, without limitation, the fees, costs and expenses of attorneys, accountants and experts, whether or not litigation is instituted, and including such fees, costs and expenses of appeals.

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IN WITNESS WHEREOF, the parties to this Agreement have executed this Employment Agreement as of the date first above written.

AMERICAN PHARMACEUTICAL PARTNERS, INC.

By /s/ Patrick Soon-Shiong

Its Chairman

Address for Notices:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Facsimile:

/s/ Alan L. Heller

ALAN L. HELLER

Address for Notices:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Facsimile:

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EXHIBIT A  
DEFINITIONS

**“Accrued Compensation”** shall mean (i) all base salary and vacation pay accrued through the Termination Date and (ii) reimbursement for reasonable and necessary expenses incurred by the Executive on behalf of the Company during the period ending on the Termination Date.

**“Base Amount”** shall mean the amount of Executive’s annual base salary at the rate in effect on the Termination Date.

**“Board”** means the Board of Directors of the Company.

**“Bonus Amount”** shall mean (i) if the Termination Date occurs after the payment to the Executive of the annual incentive payment under the Company’s cash bonus incentive plan with respect to 2006, an amount equal to the average of the last two annual incentive payments paid or payable to the Executive prior to the Termination Date, (ii) if the Termination Date occurs after the payment to the Executive of the annual incentive payment under the Company’s cash bonus incentive plan with respect to 2005 (but prior to the payment with respect to 2006), an amount equal to such payment.

**“Cause”** shall mean any of the following (i) Executive commits a material breach of this Agreement, the Confidentiality Agreement, or any policy of the Company, which breach is not cured to the satisfaction of the Board within twenty days after written notice to Executive from the Company; (ii) the Executive fails (other than a failure resulting from a Disability) to substantially perform his duties hereunder, or to implement or follow a lawful policy or directive of the Company, and such failure continues for a period of twenty days after written notice to Executive from the Company; (iii) the Executive is indicted for a crime involving dishonesty, breach of trust, physical harm to any person or serious moral turpitude, (iv) the Executive engages in dishonesty, gross negligence or willful misconduct in the performance of his duties, as reasonably determined by the Board, (v) the Executive engages in conduct which is materially injurious to the Company (monetarily or otherwise) or which constitutes a material violation of federal or state law relating to the Company or its business.

**“Common Stock”** shall mean the Company’s Common Stock

**“Disability”** means (i) the Executive becomes eligible for the Company’s long term disability benefits or (ii) in opinion of the Board, Executive has been unable to carry out the responsibilities and functions of the position held by Executive by reason of any physical or mental impairment for more than ninety consecutive days or more than one hundred and twenty days in any twelve-month period.

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“**EBITDA**” shall mean, with respect to any fiscal year of the Company, the Company’s earnings before interest, taxes, depreciation and amortization, as such amount is determined by the Company’s independent auditors based on information contained in the Company’s audited financial statements (which determination, absent manifest error, shall be conclusive).

“**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

“**Good Reason**” means, without the Executive’s express written consent, the occurrence of any of the following circumstances: (i) there is a change in the Executive’s status or responsibilities which represents a material and adverse change from the Executive’s status or responsibilities, (ii) the Executive’s base salary is reduced to a level below that in effect at any time previously (except to the extent such reduction is part of a comprehensive reduction in salary applicable to employees of the Company generally so long as the reduction applicable to the Executive is comparable to the reduction applied to other senior executives of the Company); or (iii) the Executive is required to be based at any place outside a 50-mile radius from the Executive’s then-current principal office without his written consent, except for travel that is reasonably necessary in connection with the Company’s business; (iv) the Board removes the Executive from the office of Chief Executive Officer; (v) the failure of the Board to nominate the Executive for reelection to the Board and recommend to the Company stockholders that they vote in favor of the Executive’s reelection to the Board (after the Company’s 2004 stockholder meeting); (vi) or the failure of the Company to obtain a satisfactory agreement from any successor to assume and agree to perform this Agreement, or (vii) there is a change in the Executive’s reporting relationship such that he is not reporting directly to the Board (or to the Chairman of the Board).

“**Pro-Rata Bonus**” means an amount equal to the Bonus Amount multiplied by a fraction the numerator of which is the number of days in the fiscal year through the Termination Date and the denominator of which is 365.

“**Severance Period**” shall mean, for the purposes of Section 7(b), the period commencing on the Termination Date and ending on the second anniversary of such Termination Date.

“**Stock Incentive Plan**” means the Company’s 2001 Stock Incentive Plan, as such may be amended from time to time.

“**Termination Date**” means the date on which the Executive’s employment is terminated pursuant to Section 6 hereof.

EXHIBIT B  
RELEASE

In consideration for the payments described in Section 7 of the Agreement, the Executive hereby releases and discharges American Pharmaceutical Partners, Inc., and any subsidiaries or affiliates thereof (collectively the "Company"), and their respective directors, officers, employees, benefit plans and administrators, successors and assigns from any and all claims, obligations, and liabilities, whether known or unknown, at law or in equity, arising out of the Executive's employment with the Company and the termination thereof. This Release is to be broadly construed so as to resolve all pending or potential disputes including, but without limiting the generality of the foregoing, any and all claims under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act of 1990, Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, the Employee Retirement Income Security Act of 1974, the Equal Pay Act, the Family and Medical Leave Act, the discrimination and wage payment laws of the State of Illinois, and any other statute, regulation, or ordinance, and any and all claims based upon alleged wrongful or retaliatory discharge, negligence, intentional infliction of emotional distress, defamation, invasion of privacy, other torts, harassment, employment discrimination or breach of contract (express or implied). Notwithstanding the foregoing, Executive does not waive any rights Executive may have to enforce the terms of the Transition Agreement, to benefits available after termination under any Company-sponsored employee benefit plan, to insurance protection and/or indemnification for actions taken by the Executive while an employee, officer and/or director of the Company or to make any claims for workers' compensation.

Executive acknowledges and agrees that: (a) Executive has read and understands this Release in its entirety; (b) Executive has been advised in writing to consult with an attorney concerning this Release before signing it. This subparagraph constitutes such written advice; (c) Executive has twenty-one (21) calendar days after receipt of this Release to consider its terms before signing it; (d) nothing contained in this Release waives any claim that may arise after the date of its execution; and (e) Executive executes this Release knowingly and voluntarily, without duress or reservation of any kind, and after having given the matter full and careful consideration.

Executive has the right to revoke this Release in full within seven (7) calendar days of executing it. Any revocation must be personally delivered to \_\_\_\_\_, or [his/her] designee, or mailed to American Pharmaceutical Partners, Inc., 1101 Perimeter Drive, Suite 300, Schaumburg, IL 60173-5837, and postmarked within seven (7) calendar days of the date of execution of this Release. None of the terms and provisions of this Release shall become effective or be enforceable until such revocation period has expired;

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EXHIBIT C

ARBITRATION

1. Any controversy or claim arising out of, relating to or in connection with this Agreement, or the breach thereof, shall be settled by arbitration administered by the American Arbitration Association (“AAA”) in accordance with its then existing Commercial Arbitration rules and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

2. It is the express agreement of the parties that the provisions of this Section, including the rules of the AAA, as modified by the terms of this Exhibit C, shall govern the arbitration of any disputes arising pursuant to this Agreement. In the event of any conflict between the law of the State of Illinois, the law of the arbitral location, and the U.S. Arbitration Act (Title 9, U.S. Code), with respect to any arbitration conducted pursuant to this Agreement, to the extent permissible, it is the express intent of the parties that the law of Illinois, as modified herein, shall prevail. Either party (the “Initiating Party”) may commence an arbitration by submitting a Demand for Arbitration under the AAA Rules and by notice to the other Party (the “Respondent”) in accordance with Section 16. Such notice shall set forth in reasonable detail the basic operative facts upon which the Initiating Party seeks relief and specific reference to the clauses of this Agreement, the amount claimed, if any, and any non-monetary relief sought against the Respondent. After the initial list of issues to be resolved has been submitted, the arbitrators shall permit either party to propose additional issues for resolution in the pending proceedings.

3. The place of arbitration shall be Chicago, Illinois, or any other place selected by mutual agreement.

4. The parties shall attempt, by agreement, to nominate a sole arbitrator for confirmation by the AAA. If the parties fail so to nominate a sole arbitrator within 30 days from the date when the Initiating Party’s Demand for Arbitration has been communicated to the other party, a board of three arbitrators shall be appointed by the parties jointly or, if the parties cannot agree as to three arbitrators within 30 days after the commencement of the arbitration proceeding, then one arbitrator shall be appointed by each of Protected Officer and the Company within 60 days after the commencement of the arbitration proceeding and the third arbitrator shall be appointed by mutual agreement of such two arbitrators. If such two arbitrators shall fail to agree within 75 days after commencement of the arbitration proceeding upon the appointment of the third arbitrator, the third arbitrator shall be appointed by the AAA in accordance with its then existing rules. Notwithstanding the foregoing, if any party shall fail to appoint an arbitrator within the specified time period, such arbitrator and the third arbitrator shall be appointed by the AAA in accordance with its then existing rules. For purposes of this Section 16,

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the “commencement of the arbitration proceeding” shall be deemed to be the date upon which the Demand for Arbitration has been received by the AAA. Any award shall be rendered by a majority of the members of the board of arbitration.

5. An award rendered in connection with an arbitration pursuant to this Section 16 shall be final and binding upon the parties, and any judgment upon such an award may be entered and enforced in any court of competent jurisdiction.

6. The parties agree that the award of the arbitral tribunal will be the sole and exclusive remedy between them regarding any and all claims between them with respect to the subject matter of the arbitrated dispute. The parties hereby waive all jurisdictional defenses in connection with any arbitration hereunder or the enforcement of any order or award rendered pursuant thereto (assuming that the terms and conditions of this arbitration clause have been complied with).

7. With respect to any award issued by the arbitrators pursuant to this Agreement, the parties expressly agree (i) that such order shall be conclusive proof of the validity of the determination(s) of the arbitrators underlying such order; and (ii) any federal court sitting in Chicago, Illinois, or any other court having jurisdiction, may enter judgment upon and enforce such order, whether pursuant to the U.S. Arbitration Act, or otherwise.

8. The arbitrators shall issue a written explanation of the reasons for the award and a full statement of the facts as found and the rules of law applied in reaching their decision to both parties. The arbitrators shall apportion to each party all costs (other than attorneys’ fees) incurred in conducting the arbitration in accordance with what the arbitrators deem just and equitable under the circumstances. The prevailing party shall be entitled to recover its attorneys’ fees from the other party. Any provisional remedy which would be available to a court of law shall be available from the arbitrators pending arbitration of the dispute. Either party may make an application to the arbitrators seeking injunctive or other interim relief, and the arbitrators may take whatever interim measures they deem necessary in respect of the subject matter of the dispute, including measures to maintain the status quo until such time as the arbitration award is rendered or the controversy is otherwise resolved. The arbitrator shall have the authority to award any remedy or relief that a court of the State of Illinois could order or grant, including, without limitation, specific performance of any obligation created under this Agreement, the issuance of an injunction, or the imposition of sanctions for abuse or frustration of the arbitration process, but specifically excluding punitive damages (the parties specifically agree that punitive damages shall not be available in the event of any dispute).

9. The parties may file an application in any proper court for a provisional remedy in connection with an arbitrable controversy, but only upon the ground that the award to which the application may be entitled may be rendered ineffectual without provisional relief.

## Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form S-8 pertaining to the American Pharmaceutical Partners, Inc. Savings and Retirement Plan of our reports dated March 10, 2005, with respect to the consolidated financial statements and schedule of American Pharmaceutical Partners, Inc., American Pharmaceutical Partners, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of American Pharmaceutical Partners, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ Ernst & Young LLP  
Chicago, Illinois  
March 10, 2005

## CERTIFICATION

I, Alan Heller, certify that:

1. I have reviewed this annual report on Form 10-K of American Pharmaceutical Partners, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2005

/s/ ALAN HELLER

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Alan Heller  
Chief Executive Officer

## CERTIFICATION

I, Nicole S. Williams, certify that:

1. I have reviewed this annual report on Form 10-K of American Pharmaceutical Partners, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2005

/s/ NICOLE S. WILLIAMS

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Nicole S. Williams  
Chief Financial Officer

**CERTIFICATION**

In connection with the periodic report of American Pharmaceutical Partners, Inc. (the "Company") on Form 10-K for the year ending December 31, 2004 as filed with the Securities and Exchange Commission (the "Report"), I, Alan Heller, Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

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

This Certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission. A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company, and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 16, 2005

/s/ ALAN HELLER

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Alan Heller  
Chief Executive Officer

## CERTIFICATION

In connection with the periodic report of American Pharmaceutical Partners, Inc. (the "Company") on Form 10-K for the year ending December 31, 2004 as filed with the Securities and Exchange Commission (the "Report"), I, Nicole S. Williams, Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

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

This Certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission. A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company, and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 16, 2005

/s/ NICOLE S. WILLIAMS

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Nicole S. Williams  
Chief Financial Officer

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