

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K

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12-31-03

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

For the fiscal year ended December 31, 2003

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

For the transition period from _____ to _____

PROCESSED

Commission File Number 0-21185



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FINANCIAL

aaiPharma Inc.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

04-2687849

(I.R.S. employer identification no.)

2320 Scientific Park Drive, Wilmington, NC 28405

(Address of principal executive offices) (Zip code)

(910) 254-7000

(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, \$0.001 PAR VALUE 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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2)

Yes No

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2003, computed by reference to the closing price of the common stock on that date was \$165,449,708.

The number of shares outstanding of registrant's common stock as of May 31, 2004 was 28,585,582 shares.

Explanatory Note

We are restating our financial statements for the year ended December 31, 2002 and for the first, second and third quarters of 2002 and 2003. This restatement is reported in this Annual Report on Form 10-K for the year ended December 31, 2003 and will be reported in amendments to our Quarterly Reports on Form 10-Q for the periods ended March 31, 2003, June 30, 2003 and September 30, 2003. This restatement:

- corrects the recognition of revenue for certain transactions in 2003 that did not satisfy all of the conditions for revenue recognition contained in SFAS 48 and/or SAB 101,
- increases reserves for product returns and makes other adjustments to our revenue reserves in 2003, and
- with respect to 2002 and 2003, changes the accounting for our major product line acquisitions which had been accounted for as business combinations to treat such acquisitions as acquisitions of assets that do not constitute a business.

On February 27, 2004, our Board of Directors appointed a committee consisting of all of the non-employee members of our Board of Directors (the "Special Committee") to conduct an inquiry into unusual sales in our Brethine and Darvocet product lines during the second half of 2003. King & Spalding LLP, an independent law firm, and Deloitte & Touche USA LLP, as independent forensic accountants, were engaged to assist the Special Committee in this inquiry.

In connection with the Special Committee's inquiry, we determined that certain matters required material adjustments to the 2003 financial information included in our February 5, 2004 press release and the financial information for the periods ended March 31, June 30, and September 30, 2003. The Special Committee's investigation and the adjustments from the Special Committee's inquiry are discussed in greater detail in this report in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Special Committee Investigation."

In addition to the accounting treatment adjustments identified in connection with the Special Committee's investigation, we have identified several other adjustments that affect the 2003 financial information that we had reported on February 5, 2004. These adjustments include:

- a charge of \$15.9 million due to the impairment of our Brethine intangible asset recorded in the fourth quarter of 2003;
- a \$4.7 million impairment charge in the fourth quarter of 2003 which represents the entire intangible asset recorded in the third quarter relating to the acquisition of Darvocet A500;
- a \$7.3 million increase in our returns reserve for sales of Brethine and Darvon/Darvocet products in the fourth quarter of 2003;
- a \$2.7 million increase in our inventory obsolescence reserve in the fourth quarter of 2003;
- a \$3.2 million increase in our chargeback reserve for sales in the fourth quarter of 2003 for our Oramorph product and other products; and
- a valuation allowance of \$10.0 million as an offset against our deferred tax asset as of December 31, 2003.

In addition to the 2003 adjustments arising in connection with the Special Committee's investigation and the additional adjustments identified above, we are restating our financial statements for the year ended December 31, 2002 and for the periods ended March 31, June 30, and September 30, 2002 and 2003 to treat

each of our major product line acquisitions as acquisitions of assets that do not constitute a business. On January 14, 2004 and April 26, 2004, we received letters from the SEC's Division of Corporate Finance commenting on, asking questions about, and seeking additional disclosure with respect to, certain of our periodic reports. Following discussions with the Division of Corporate Finance and based on additional analyses, we have changed our accounting for these transactions from treating the acquisitions as business combinations to treating them as asset acquisitions. Accordingly, no portion of the purchase price for these acquisitions is allocated to goodwill, and the amount previously allocated to goodwill is instead allocated to the other identifiable acquired assets, including assets with definite lives. As a result, our direct costs in 2002 are greater than the amount previously reported by \$6.8 million due to the increase in amortization expense resulting from a greater amount of purchase price being allocated to assets with definite lives, and our direct costs in 2003 are greater than the amount we reported in our February 5, 2004 press release for 2003 by \$9.1 million.

As a result of the foregoing, we have reduced our 2003 net revenue and diluted earnings per share by \$57.7 million and \$2.35, respectively, from the results we reported in our February 2004 press release. Our 2003 net revenues and diluted loss per share are \$225.0 million and \$1.18, respectively. For more detail on the adjustments we have made to the 2003 financial information that we had reported in our February 5, 2004 press release, see the table included in this report in "Item 7. Management's Discussion and Analysis of Financial Condition and Results at Operations – Restatement of Previously Issued Financial Statements" and Note 1 of Notes to Consolidated Financial Statements included elsewhere in this report. In addition, we have reduced our 2002 diluted earnings per share by \$0.15 from the results reported in our annual report on Form 10-K for the year ended December 31, 2002 and are now reporting diluted earnings per share of \$0.46. The financial results reported in this report have incorporated these adjustments.

Until we amend our Quarterly Reports on Form 10-Q for the periods ended March 31, 2003, June 30, 2003 and September 30, 2003, the financial statements and related financial information contained in such reports should not be relied upon. In addition, we do not intend to file any amended Annual Report on Form 10-K or Quarterly Report on Form 10-Q for periods affected by the restatements that ended prior to March 31, 2003, and the financial statements and related financial information contained in such reports should no longer be relied upon.

All referenced amounts in this report for prior periods and prior period comparisons reflect the balances and amounts on a restated basis.

PART I

Item 1. Business

The terms "we", "us", "our" or "aaiPharma" in this Form 10-K include aaiPharma Inc., its corporate predecessors and its subsidiaries, except where the context may indicate otherwise. Our corporation was incorporated in 1986, although its corporate predecessor was founded in 1979. In 1999, we merged with Medical & Technical Research Associates, Inc.

Our principal executive offices are located at 2320 Scientific Park Drive, Wilmington, North Carolina (telephone: 910-254-7000).

Our Internet address is www.aaiPharma.com. We make available through our internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934 as soon as

reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission.

Trademarks and Trade Names

We own the following registered and unregistered trademarks: Darvocet™, Darvon®, Darvon-N®, Darvocet-N®, Darvocet A500™, Brethine®, ProSorb®, ProSorb-D™, ProSLO™, ProSLO II™, ProCore®, Oramorph® SR, ProLonic AQ™, Roxanol™, Roxicodone®, AzaSan®, aaiPharma®, AAI® and Applied Analytical Industries®. AzaSan® is a registered trademark owned by us and licensed to Salix Pharmaceuticals. Unless the context otherwise requires, references in this document to Darvon are to Darvon® and Darvon-N® collectively and references to Darvocet are to Darvocet-N® and Darvocet A500™. We also reference trademarks owned by other companies. Prilosec® is a registered trademark of AstraZeneca AB, Dolophine® is a registered trademark of Eli Lilly and Company, Allegra-D® is a registered trademark of Aventis Pharmaceuticals Inc., Proventil® is a registered trademark of Schering Corporation, Volmax® is a registered trademark of GlaxoSmithKline, Ultram® is a registered trademark of Johnson & Johnson, Imuran® is a registered trademark of Prometheus Laboratories Inc., M.V.I.® and Aquasol® are registered trademarks owned by Mayne Pharma (USA) Inc., Duraclon® is a registered trademark owned by Fujisawa Healthcare, Inc. and licensed to us, Avinza® is a registered trademark owned by Ligand Pharmaceuticals, Inc., MS Contin® and Oxycontin® are registered trademarks owned by Purdue Pharma, L.P., Kadian® is a registered trademark owned by Alpharma Inc., Zemplar® and Calcijex® are registered trademarks owned by Abbott Laboratories, and Hectorol® is a registered trademark owned by Bone Care International Inc. All references in this document to any of these terms lacking the “®” or “™” symbols are defined terms that reference the products, technologies or businesses bearing the trademarks with these symbols.

Overview

Our company was founded in 1979 to provide laboratory services, such as analytical testing on pharmaceutical compounds, to pharmaceutical companies. In the 1980s, we increased our service offerings to include clinical trials material manufacturing, microbiological testing and regulatory and quality consulting. We continued expanding our scientific base in the 1990s by adding bioanalytical, biotechnical, commercial manufacturing and human clinical trials management capabilities. We offer our clients scientific solutions to their pharmaceutical development needs. In our history, we have worked with large and small companies offering a wide range of services across the drug development continuum.

We also used our drug development capacity to work on our own internal product pipeline. In the 1990s, we helped establish two companies which received approvals for products we developed. We also entered into various shared-risk arrangements with companies to bring pharmaceutical products to the market based on development work we conducted.

In 2001, we began pursuing a product acquisition strategy. Between August 2001 and April 2002, we acquired three product lines, which we initially marketed through a contract sales force. In late 2002, we decided to augment sales of our products by creating an internal sales and marketing capability. In late 2003, we completed the acquisition of a line of pain products from Elan. This acquisition opened the hospital channel for promotion of a sophisticated line of injectable products used to treat pain. These products are mainly used in hospital settings and the hospital market will be the focus of our pharmaceutical operations in 2004.

We operate through the following businesses:

- Pharmaceuticals Division;
- AAI Development Services; and

- Research and Development Division.

For information about the revenues, income from operations and total assets of each segment of our business for each of the last three years, see Note 12 of Notes to Consolidated Financial Statements included elsewhere in this report.

Vision and Strategy of our Company

We envision aaiPharma as a science-driven pharmaceutical company focused on developing medicines that minimize or eliminate pain in patients. The business model of our company is unique and incorporates significant third party utilization of our drug development capabilities and our facilities in exchange for fees and royalties, which we use to offset the overhead costs of our company and our research and development program.

Our company has extensive pharmaceutical development experience and has been part of the development program on numerous products for major pharmaceutical companies for over 20 years. We plan to leverage that experience, our own intellectual properties and our relationships with other pharmaceutical companies to grow our company by developing our own novel product portfolio and by acquiring existing products and improving them.

We plan to commercialize our own pharmaceuticals in three ways:

- First, we are continuing to build a hospital-based sales force focused on pain products. This sales force will continue to consist of highly trained and skilled professional representatives who work directly for our company. We do not anticipate utilizing contract sales organizations. Our sales representatives will be focused on the needs of physicians who treat acute and chronic pain using a consultative sales approach. We will augment the sales force with seminars and visits from our pool of scientific and medical talent resident in our laboratories.
- Second, we will seek pharmaceutical partners to sell some of our products to the wider markets including family practice physicians. The Company currently has several approved products and several pipeline products that will benefit from this co-marketing and/or co-promotion approach. Conversely, we will seek agreements with pharmaceutical companies to market their products into the hospital market utilizing our own specialty sales force.
- Third, we intend to license some of our products to other parties in exchange for fees and royalties and in some cases in exchange for product rights to their products. International license agreements for existing and pipeline products are anticipated along with domestic licenses for products outside of our therapeutic focus.

We plan to focus our research and development efforts toward improved pain therapeutics, although we will continue a broader research effort in other therapeutic areas such as gastrointestinal disease and central nervous system disorders. We will continue to research physical chemical attributes of various pharmaceuticals and broaden our intellectual property base.

Pharmaceuticals Division – Our Product Sales Business

The Pharmaceuticals Division markets and commercializes the pharmaceutical products that we have acquired or developed. In 2004, we made a strategic decision to refocus our sales force to the hospital and pain clinic markets following our acquisition of Duraclon, Oramorph SR and a methadone injectable product. Our sales force is being redesigned to provide experienced and knowledgeable professionals to sell our complex, highly technical specialty pharmaceutical products to a sophisticated target market. We believe that this new, narrower focus will create greater efficiencies for our sales team and allow us a forum

to discuss the clinical benefits of our products. To improve the selling efforts of our proprietary branded products, such as the Darvon and Darvocet brands, and our near term pipeline products, we will seek to identify and team with a long term marketing alliance partner to market and sell to primary care physicians.

Consistent with our scientific and clinical orientation we will expand our medical affairs resources to support and improve the clinical application and utilization of our products to benefit patients.

We commercialize products in the pain and critical care therapeutic areas. Our pain products include both Schedule IV drugs, (Darvon/Darvocet), and Schedule II products acquired from Elan. Our critical care products are used to treat chronic kidney dialysis patients (calcitriol), organ rejection in kidney transplants (azathioprine) and severe asthma (Brethine). We are aware that our Brethine injectable product is prescribed by doctors for off-label usage to treat premature labor.

Sales and Distribution of Pharmaceutical Products

We use an internal sales force to sell our pharmaceutical product lines. As mentioned above, we are redesigning our sales efforts to reach hospitals and pain clinics.

As of May 12, 2004, we had 75 sales representatives. We have contracted with a subsidiary of Cardinal Health, Inc. to provide warehousing, distribution, inventory tracking, customer service, and financial administrative assistance related to our distribution program, including management of applicable chargebacks, and accounts receivable collection.

On December 26, 2003 we entered into an agreement with a second subsidiary of Cardinal Health, Inc., effective as of October 1, 2003, to act as our exclusive distributor of Brethine injectable products in their 10-pack presentation for a three-year period.

Manufacturing Capability

We currently manufacture certain high-potency and high-toxicity drug products, along with controlled substance products, for ourselves and for clients in our manufacturing facility in Wilmington, North Carolina. Although our manufacturing generally covers small volume products, our manufacturing capability has been upgraded to allow manufacture of a portion of the Darvon and Darvocet family of products in our own facility. We also manufacture certain drugs developed on behalf of clients for commercial sale and we provide manufacturing, packaging, and labeling of clinical trial materials. In addition, we also operate a 48,000-square-foot sterile manufacturing facility in Charleston, South Carolina where we manufacture sterile, injectable products, including our methadone hydrochloride product and our Brethine injectable product.

Our Pharmaceutical Products

We commercialize products in two therapeutic areas, pain management and critical care.

Pain Management Products

Roxicodone, Oramorph SR, Roxanol and Duraclon Product Lines. On December 2, 2003, we acquired a line of pain management products, which treat moderate-to-severe pain (the "New Pain Products"), and existing inventory from subsidiaries of Elan Corporation, plc. We acquired these product lines, inventory and related intangible assets for \$102.5 million, exclusive of transactional costs. These products consist of three brands of Schedule II (CII) pain products -- Roxicodone (oxycodone hydrochloride) tablets, Oramorph SR (morphine sulfate) sustained-release tablets, and Roxanol (morphine sulfate) immediate release oral solutions. We also acquired a non-scheduled pain management product, Duraclon (clonidine hydrochloride) injection, as part of the same transaction. Schedule II pain products are regulated as controlled substances

by the U.S. Drug Enforcement Agency. Each of these products, other than Oramorph SR, is subject to generic competition. Oramorph SR is subject to substitution by pharmacists in certain states.

Supply of Product. The New Pain Products are manufactured and supplied by third parties. Duraclon is currently purchased on a purchase order basis from American Pharmaceutical Partners, Inc. Roxicodone, Oramorph SR, and Roxanol are purchased pursuant to a manufacturing agreement between Roxane Laboratories, Inc. ("Roxane") and Elan Pharma International Limited dated September 28, 2001 (the "Roxane Supply Agreement"). We assumed Elan Pharma International Limited's rights and obligations under the Roxane Supply Agreement in connection with the acquisition of the New Pain Products. The term of the Roxane Supply Agreement expires on September 27, 2006. Roxane manufactures the applicable New Pain Products in its Columbus, Ohio facility.

Darvon and Darvocet. On March 28, 2002, we acquired from Eli Lilly the U.S. rights to the Darvon and Darvocet branded product lines in the U.S. (and the existing inventory of these products). The Darvon and Darvocet products are prescribed for the treatment of mild-to-moderate pain. The acquired products include Darvon (propoxyphene hydrochloride), Darvocet-N (propoxyphene napsylate and acetaminophen), and Darvon-N (propoxyphene napsylate).

These product lines have been sold in the U.S. for over 25 years, with the initial marketing of Darvon beginning in 1957. Darvon's patent exclusivity expired in 1973 and Darvon-N and Darvocet-N's patent exclusivity expired in 1985. The first generic version of Darvon was introduced in 1973, and by 1985, numerous generic products were being marketed for substitution for Darvon and Darvocet. We believe that Eli Lilly ceased actively promoting these brands in approximately 1993.

We paid \$211.4 million in cash, exclusive of transactional costs, for the rights in the U.S. to these products and Eli Lilly's existing inventory of these products. In addition, we have agreed to pay Eli Lilly royalties upon sales of our future developed improvements to the Darvon and Darvocet products or other products containing the active ingredient propoxyphene and any other pharmaceutical products sold under the name Darvon, Darvocet or certain other trademarks. We will pay additional royalties for future products during each calendar quarter for a ten-year period beginning upon the product's commercial introduction, provided that the total net sales of all of these future products, combined with the total net sales of the current Darvon and Darvocet products, exceed \$15.0 million in the applicable calendar quarter. We do not owe any royalties on the sales of the Darvon and Darvocet products themselves that we acquired from Eli Lilly.

Supply of Product. Under a manufacturing agreement, as amended, that we have entered into with Eli Lilly, Eli Lilly agreed to supply specified quantities of the acquired products and the bulk active ingredient from and after closing for the then-existing twelve Darvon and Darvocet product presentations (form and dosage). The supply agreement extends through December 31, 2004. We purchase these products manufactured by Eli Lilly for a fixed unit cost, subject to a percentage increase on each January 1 plus any increase in Eli Lilly's cost of raw materials during that year. However, the purchase price for these products is no less than Eli Lilly's standard cost of manufacturing, which includes raw materials, direct labor, and plant overhead attributable to the Darvon and Darvocet products. We have acquired all of the product under this agreement that we will need for 2004, except for the requirements of one product which we are manufacturing in one of our manufacturing facilities. We intend to transfer into our facility the manufacturing of all products previously manufactured by Eli Lilly, except one product which will be manufactured by a third party. The transfer of this manufacturing, however, is subject to FDA approval and it is possible that this approval could require significant expense and time, and it is possible that we might never receive approval.

Darvocet A500. We acquired a product which we subsequently branded as Darvocet A500 from Athlon Pharmaceuticals in July 2003. Due to safety concerns about the potential for liver toxicity from large doses of acetaminophen, the FDA established a recommended 4,000 mg maximum daily dose limit of over-the-

counter acetaminophen for adults. Containing only 500 mg of acetaminophen, compared to 650 mg in Darvocet-N 100, Darvocet A500 taken at the recommended daily dose provides 1,000 mg less acetaminophen than the FDA limit. Because many patients continue taking over-the-counter pain relievers and sleep aids containing acetaminophen in addition to a prescription pain reliever, Darvocet A500 reduces the likelihood of exceeding the recommended daily limit for acetaminophen when taken up to six times per day, without sacrificing analgesic efficacy. We received FDA approval of Darvocet A500 on September 10, 2003, launched the product in September 2003 and initiated a national campaign in October 2003.

In connection with the acquisition, we entered a three-year services agreement with Athlon Pharmaceuticals to provide sales support in designated territories throughout the United States for the Darvocet A500 product. After providing notice to Athlon of its material breach under this agreement, we terminated this agreement on June 4, 2004 and have initiated litigation.

Supply of Product. Darvocet A500 is manufactured and supplied by Mikart, Inc. (Mikart). Mikart manufactures Darvocet A500 in its Atlanta, Georgia facility. We have entered into an agreement with Mikart to supply us with our requirements for Darvocet A500 for an initial term ending 2013. Thereafter, the agreement with Mikart will continue for successive one-year renewal terms unless terminated by either party as set forth in the agreement. The agreement requires us to make a payment to Mikart if we have not purchased a set amount of Darvocet A500 by September 2006. We have amended this agreement in 2004 to allow additional products of ours to be manufactured by Mikart and for these products to be included in our purchase obligation although we have not yet agreed on the terms for manufacturing these additional products, including price.

Methadone Hydrochloride Injection. In April 2003, we acquired exclusive rights to a parenterally administered methadone product, formerly branded as Dolophine Hydrochloride Injection, from Roxane. This product is indicated for the treatment of moderate-to-severe pain not responsive to non-narcotic analgesics, and for use in temporary treatment of opioid dependence in patients unable to take oral medication.

We manufacture this product at our facility in Charleston, South Carolina.

Critical Care Products

Brethine. On December 13, 2001, we acquired the U.S. rights to the Brethine branded product line from Novartis Pharmaceuticals Corporation and Novartis Corporation for \$26.6 million in cash, exclusive of transactional costs. Brethine, or terbutaline sulfate, is a beta-adrenergic agonist bronchodilator, meaning that it aids in the flow of air through the bronchial tubes for people suffering from asthma, emphysema, chronic bronchitis, and other lung diseases. Brethine is approved in oral and injectable forms for the prevention and reversal of bronchospasm in patients age 12 and older with asthma and reversible bronchospasm associated with bronchitis and emphysema. Although physicians also prescribe Brethine to stop premature labor, this drug has not been approved by the FDA for this indication and thus we do not market or promote the product for this use. Brethine was initially marketed beginning in 1975. We believe that Novartis ceased actively promoting Brethine in the early 1990s, although Novartis selectively marketed and promoted Brethine since then and a third party provided marketing support for Brethine during 1999 and 2000.

IMPAX Laboratories has been marketing a generic version of the oral form of Brethine since July 2001. Two generic versions of the injectable form of this drug were approved in 2004. Major branded products competing against Brethine to treat these ailments include Volmax, Proventil, and branded and generic forms of albuterol.

Supply of Product. We entered into an interim supply agreement with Novartis providing for manufacture and packaging of the oral and injectable form of Brethine for sale by us in the U.S. through December 13, 2004. Under the supply agreement, we may purchase the products for a fixed unit cost during the term of the agreement, that was subject to an annual price adjustment on January 1, 2003 and January 1, 2004 tied to the Consumer Price Index. We have transferred the Brethine manufacturing processes to our own facility.

Calcitriol. On February 13, 2002, we acquired from Aesgen, Inc. the rights to its calcitriol product, a generic injectable vitamin D nutritional product. This product is used primarily to treat chronic kidney dialysis patients with abnormally low levels of calcium in their circulating blood. We paid \$1.0 million for this product at the time of acquisition and agreed to make additional contingent milestone payments of up to \$1.5 million and royalty payments for the eight-year period following the first commercial sale of this product. In 2003, the prerequisite for payment of an additional \$500,000 of such contingent milestones occurred and such payment was made to Aesgen, while the prerequisites for payment of the remaining \$1.0 million were not met and no further payment of this amount is owed by us.

On February 20, 2003, we were notified by the FDA of marketing approval for our calcitriol product, with shared 180-day marketing exclusivity for this drug product with a second company. No other companies were approved for the sale of calcitriol until the expiration of this market exclusivity period, after which time additional generic calcitriol products competing with our calcitriol product were approved for commercial sale by the FDA. In March 2003, we commenced commercial sales of our calcitriol product and also entered into a long-term manufacturing and co-promotion agreement with another company with respect to such other company's calcitriol product under their regulatory approval. The exclusivity period ended in the second half of 2003.

Azathioprine. In 2003, we received FDA approval to market three internally developed line extensions of additional strengths to our current 50 mg generic azathioprine tablet product: 25 mg, 75 mg and 100 mg tablets. We began selling the 75 mg and 100 mg products in the first quarter of 2003. Azathioprine is an immunosuppression agent used in the prevention of organ rejection in kidney transplants and for the management of severe, active rheumatoid arthritis unresponsive to rest, aspirin or other nonsteroidal anti-inflammatory drugs, or NSAIDs. In November 2003, we granted Salix Pharmaceuticals an exclusive license to market the 25 mg, 75 mg, and 100 mg strengths of AzaSan (azathioprine) and we licensed our AzaSan trademark to Salix. Under the agreement with Salix, we receive royalties on net sales. We entered into a three-year supply agreement with Salix to continue to manufacture these products and supply all of Salix's needs. We continue to manufacture and sell our 50 mg azathioprine tablet product as a generic product.

M.V.I. and Aquasol. On August 17, 2001, we acquired the M.V.I. and Aquasol branded lines of critical care injectable and oral nutritional products from AstraZeneca for \$52.5 million, exclusive of transactional costs, paid at closing, plus additional consideration described below. Our M.V.I. and Aquasol product line acquisition agreement was amended on July 22, 2003. As amended, it provided for two \$1.0 million guaranteed payments, which were made in August 2002 and 2003, eliminated a contingent payment of \$2.0 million that was potentially due in August 2003 under the original agreement, and provided for a future contingent payment of \$43.5 million potentially due in August 2004, depending on the status of certain reformulation activities being carried out by the seller and regulatory approval of the reformulation by the FDA. The amount of the \$43.5 million contingent payment was to be reduced by \$1 million per month if the conditions for the contingent payment had not occurred by December 31, 2002. The conditions for the contingent payment were not met by the required date, so the amount of the contingent payment had decreased by \$12.0 million by the end of December 2003. Such conditions were satisfied in January and February 2004, fixing the liability at \$31.5 million. As of December 31, 2003, this contingent obligation had not been recorded as a liability on our consolidated balance sheet and will be recorded in the first quarter of 2004. Also on July 22, 2003, the M.V.I. supply agreement with the seller was extended through 2008, subject to early

termination rights by us on six months' notice given at any time, and by the supplier on twenty-four months notice given at any time on or after August 17, 2004. The M.V.I. and Aquasol product lines did not have separable assets and liabilities associated with them other than inventory; therefore we allocated the remaining purchase price to acquired identifiable intangible assets.

On April 26, 2004, we sold our M.V.I. and Aquasol product lines (the "M.V.I. and Aquasol Sale") to Mayne Pharma (USA) Inc. for \$105 million, subject to adjustments based on inventory levels at closing and other post-closing obligations. A portion of the closing payment is held in escrow to satisfy our post-closing obligations under the agreement. At the closing of the transaction, we paid to AstraZeneca AB the \$31.5 million payment due in August 2004, which was discounted to approximately \$31.0 million (the "M.V.I. Payment"). The M.V.I. Payment represents a payment upon FDA approval of the reformulated product under the terms of the amended purchase agreement with AstraZeneca.

AAI Development Services — Our Development Services Business

AAI Development Services offers a comprehensive range of pharmaceutical product development services to our customers on a worldwide basis. These services include formulation development, analytical, microbiological, bioanalytical and stability testing services, production scale-up, biotechnology analysis and synthesis, human clinical trials, regulatory and quality consulting, and manufacturing. These services generally are provided on a fee-for-service basis.

Prior to our transition to a specialty pharmaceutical company, this development services business was the core of our operations. AAI Development Services provides its services, both individually and in an integrated fashion, to:

- our customers, to help them develop, control, and improve their drug products;
- our Pharmaceuticals Division, to manufacture and improve its acquired drug products; and
- our Research and Development activities, to assist in development of drugs and drug-delivery technologies and product life cycle management activities.

Since our founding in 1979, we have contributed to the submission, approval or continued marketing of many client products, encompassing a wide range of therapeutic categories and technologies. We believe that our ability to offer an extensive portfolio of high quality drug development and support services enables us to effectively compete as pharmaceutical and biotechnology companies look for a mixture of stand-alone and integrated drug development solutions that offer cost-effective results on an accelerated basis.

We have a strong base of resources, expertise, and ideas that allows us to develop and improve drug products and carry out product life cycle management activities both for our customers and ourselves. Our expertise covers many therapeutic categories and types of pharmaceutical products. We are expanding our expertise in the key therapeutic area of pain management to further enhance our products in this area.

We focus on our customers' individual needs when marketing our services, often placing our technical personnel with our clients' development teams to participate in planning meetings for the development or improvement of a product. We assign our sales and technical personnel as contacts for our larger clients, understanding that technical personnel may be better able to identify the full scope of our client's needs and suggest innovative approaches. Additionally, we host several technical seminars each year to help our customers stay abreast of the latest developments in their industries.

Generally, AAI Development Services' fee-for-service contracts are terminable by the client upon notice of 30 days or less. Although the contracts typically permit payment of certain fees for winding down a project or for work incurred to date, the loss of a large contract or the loss of multiple contracts could adversely

affect our future revenue and profitability in our development services business. Contracts may be terminated for a variety of reasons, including the client's decision to stop a particular study, the failure of product prototypes to satisfy safety requirements, and unexpected or undesired results of product testing.

AAI Development Services' core services are organized internally along pharmaceutical, analytical, biopharmaceutical, clinical and regulatory affairs lines to mirror the movement of pharmaceutical products through the drug development pipeline.

Pharmaceutical Services

AAI Development Services provides a variety of pharmaceutical services to its customers, including drug formulation development and small scale manufacturing, as well as storage and distribution of clinical trial supplies. The services are organized to help clients from the pre-clinical to post-marketing stages.

Formulation Development Services. AAI Development Services provides integrated formulation development services for customers' pharmaceutical products to develop safe and stable products with desired characteristics. AAI Development Services provides services during each phase of the drug development process, from new compounds to modifications of existing products. These formulation development projects may last for a short duration or for several years.

Manufacture of Clinical Trial Supplies. AAI Development Services manufactures clinical trials materials for Phase I through IV drug-product clinical trials. It has expertise in manufacturing tablets, capsules, sachets, liquids and suspensions, creams, gels, lotions and ointments. Outsourcing of clinical supply manufacturing is particularly attractive to pharmaceutical companies that maintain large, commercial-quantity, batch facilities, where clinical supply manufacturing would divert resources from revenue-producing manufacturing. AAI Development Services has a dedicated 25,000 square foot facility in Wilmington, North Carolina and another facility in Neu-Ulm, Germany to distribute and track clinical trial materials used in clinical studies. Additionally, they have the capacity for controlled substance storage and handling. AAI Development Services provides its clients with assistance in scaling up production of clinical supply quantities to commercial quantity manufacturing and provides small batch commercial manufacturing capabilities.

Analytical Services

AAI Development Services provides a wide variety of analytical services, as well as services pertaining to method development and validation, drug product and active pharmaceutical ingredient characterization and control, microbiological support, stability storage and studies, technical support and problem solving. Our analytical services include:

- Method development and validation;
- Product characterization;
- Raw materials and product release testing; and
- Stability studies.

Biopharmaceutical Services

AAI Development Services integrates a Phase I clinical study capability with bioanalytical and biotechnology expertise to provide biopharmaceutical services to its customers. The analysis of drugs, metabolites, and endogenous compounds in biological samples is a core service. Our biopharmaceutical services include:

- Phase I clinical services from our 88-bed Phase I clinical trial facility located in Research Triangle Park, North Carolina, and a 72-bed facility in Neu-Ulm, Germany;
- Microbiological testing;

- Bioanalytical testing; and
- Biotechnology analysis and synthesis.

Phase I to IV Clinical Services

AAI Development Services provides a broad range of Phase I through IV clinical services to customers in the pharmaceutical, biotechnology, and medical device industries for assistance in the drug development and regulatory approval process in North America. The clinical services include clinical trial management and monitoring, site selection, medical affairs (including safety surveillance and serious adverse event management), data management and statistics.

Regulatory and Other Consulting Services

AAI Development Services provides consulting services with respect to regulatory affairs, quality compliance, and process validations. It assists in the preparation of regulatory submissions for drugs, devices and biologics, audits clients' vendors and client operations, conducts seminars, provides training courses, and advises clients on applicable regulatory requirements. AAI Development Services also assists clients in designing development programs for new or existing drugs intended to be marketed in the United States and Europe.

Research and Development Division — Our Product Development Business

The Research and Development Division provides research and development expertise that has been leveraged externally for our clients and more recently internally for our own proprietary product efforts. This division serves as the foundation for our “bridging” strategy that allows us to provide integrated new product planning services by bridging the company’s research and development capabilities with our commercialization efforts. The division has a unique portfolio of proprietary and licensed drug-delivery technologies (described below) and intellectual property rights. We offer these product improvement or life cycle management activities to our customers for royalties, milestone payments, and fees. In addition, we apply this expertise to improve our acquired products and internally develop our own new products.

In addition to product development, the Research and Development Division seeks to develop proprietary drug-delivery technologies for licensing to our clients. We also utilize our technical resources and operating capacity for internal drug and technology development with the objective of marketing new products or licensing marketing rights to third parties.

Our internal product and technology development program has resulted in multiple product applications filed with the FDA and European regulatory agencies. Many of these products have been licensed or sold. Others are still in development. The internal development program has also resulted in patents covering drugs and drug technology and numerous pending patent applications.

We have significant experience in providing product life cycle management services to our clients, which we leverage to develop our own proprietary products. Product life cycle management offers product improvement and line extension opportunities to clients, generally for marketed products facing patent expiration that could medically and commercially benefit from improvements or line extensions. Product improvements and line extensions offer clients an opportunity to improve product or product delivery characteristics, thus enhancing the medical value while extending the commercial value of a branded product line. Improved characteristics may include enhancement of product stability, creation of additional absorption profiles (e.g., quick or sustained release), higher drug absorption or bioavailability (permitting reduced drug loads per dose with the potential for lower costs and side effects), improved taste, more attractive appearance, or better dosage regimes (e.g., once a day versus multiple doses per day). Product line extensions may include new dosage forms, such as solids, liquids and chewables, to increase patient populations who can benefit from such drugs (e.g., pediatric or geriatric patient populations), as well as new

dosage strengths that may be more convenient for doctors and patients under current treatment regimens. Product modifications and line extensions offer clients the opportunity to target new patient populations and improve patient compliance and convenience. Product life cycle management activities also can lead to new inventions and discoveries in the course of the research and development work, providing new opportunities for long-term patent protection for the modified products and potential long-term value for licensees of our technologies.

Our Drug-Delivery Technologies

Our portfolio of internally developed and in-licensed drug-delivery technologies provide us with opportunities for the expansion of a drug product's effective market life. Our currently available technologies include:

- *ProCore* — a patented technology for controlled release of a drug incorporated into a two-layer coated pellet. The first layer allows for control of the lag time before an active agent begins its release while the second layer controls the rate of release, and thus the duration of the sustained release effect for the product.
- *ProSorb* — a technology designed to accelerate absorption rates. It permits weakly acidic compounds to exhibit a shorter onset of action relative to conventional dosage forms. The concept is that acidic drugs with the benefit of the technology form a dispersion pattern upon release in the stomach that allows for faster and more complete absorption. ProSorb is a broad-based technology primarily used with liquid or encapsulated drug products. The application of this technology to diclofenac, a non-steroidal anti-inflammatory drug, has resulted in our proprietary ProSorb-D product candidate, which is discussed below.
- *ProLonic AQ* — a drug-delivery technology specifically designed to release an active agent in the colon. This technology can be incorporated into a tablet, a pellet, or a capsule dosage form and uses conventional manufacturing equipment and aqueous coating processes. The advantage represented by this technology is the ability to control the location and timing of release.
- *ProSLO and ProSLO II* — an osmosis technology designed to produce controlled release product therapy with either a single drug or a combination of drugs. Osmotic action is the natural movement of an aqueous solution through a membrane and is used to make oral drug administration more accurate, precise, and convenient. This technology allows for an immediate release component in the outside layer of a laser drilled tablet. This facilitates a combination of multiple active ingredients with different release requirements. The advantages over existing technologies are its easy scalability, the ability to use it with numerous active ingredients, the ability to create both a long- and short-acting drug combination, and its ability to handle what normally are insoluble active ingredients.

We own the ProCore, ProSorb, and ProLonic AQ technologies. The ProSLO and ProSLO II technologies are available for use by us and our clients in the U.S. through an agreement with Osmotica Corporation. We have entered into a Cooperative Venture Agreement with Osmotica Corporation to develop, manufacture and license various new drug products with third party organizations. This agreement enables us to develop mutually acceptable new drug products or improve the characteristics of mutually acceptable existing products and compounds utilizing patents, patent applications and know-how associated with pharmaceutical formulation technologies for such products.

The Research and Development Division has continued our internal development of products to be licensed to third parties that have additional marketing and distribution capabilities or a therapeutic focus different than ours.

Our Internal Product Development Pipeline

We have a number of proprietary pharmaceutical products under development, in three primary categories:

- chemical compounds or existing active pharmaceutical ingredients where product line extensions or new product forms (such as different dosages, formulations or delivery mechanisms — e.g., liquids versus tablets), or combination drugs involving two known active ingredients, offer potential therapeutic or marketing advantages. Examples of this include ProSorb-D;
- new active ingredients or compounds that are chemically similar to currently marketed products with established therapeutic and safety profiles that offer improved attributes over existing products; and
- new active ingredients or chemical entities that fall within our targeted therapeutic classes.

Our product development strategy focuses on products for which we expect some period of market exclusivity, without competition from generic substitutes or other third-party products. This exclusivity may come by way of patents or regulatory exclusivity.

We are currently developing the following products:

Darvon/Darvocet Line Extension. A line extension with improved product delivery and therapeutic characteristics eligible for regulatory and patent exclusivity.

Brethine Line Extensions. We have received FDA approval of a glass vial form of an injectable Brethine product, as opposed to the current glass ampoule presentation. This form improves the safety and convenience of administering this drug. We are also working towards reducing the aluminum content in this product.

ProSorb-D. ProSorb-D is a softgel capsule that combines diclofenac, an anti-inflammatory pain medication, with our ProSorb rapid dispersion technology. This product is for the management of pain. It has recently completed Phase III clinical trials and we plan to file a New Drug Application, or NDA, with the FDA in the second half of 2004.

Gastrointestinal Product. We are developing a proton pump inhibitor, delivered in a unique formulation developed by us. The product is in clinical evaluation with filing planned in the second half of 2004.

Fexofenadine/pseudoephedrine. On January 15, 2004, we announced that Aventis submitted an NDA to the FDA for Allegra-D 24-hour tablets. This is a fexofenadine/pseudoephedrine formulation developed by us with a patented extended release drug-delivery technology, ProSLO II. Upon approval by the FDA, we will receive a milestone payment and royalties on sales of the product.

Other Product Candidates. In addition to the specifically identified products named above, we continue to target additional products to develop. As we continue our development activities, obtain additional information, and evaluate our interim results, we may decide to change the scope and direction of any of our development programs and projects. This could also change how we allocate our research and development spending. Notwithstanding the foregoing, we may not be able to successfully develop, commercialize or license any of the products discussed in this Form 10-K.

We devote significant resources to research and development. For fiscal years 2003, 2002 and 2001, our expenditures on research and development were \$21.8 million, \$20.9 million and \$10.5 million, respectively.

Information Technology

We have made significant investments in information technology. Our customized data management system connects analytical instruments with multiple software architectures permitting automated data capture. We believe that information technology enables us to expedite the development process by designing innovative services for individual client needs, providing project execution, monitoring and control capabilities that exceed a client's internal capabilities, streamlining and enhancing data presentation to the FDA and improving our own internal operational productivity, while helping to maintain quality. We continue to upgrade and expand our company-wide financial and operational integrated management information systems. Significant upgrades have begun and are scheduled to be completed during 2004.

Customers

Our largest customers are large wholesalers of pharmaceutical products. The Pharmaceuticals Division's customers are primarily large well-established pharmaceutical wholesalers. Cardinal Health, Inc., AmerisourceBergen Corporation and McKesson Corporation accounted for approximately 16.7%, 15.4% and 11.6% of our 2003 consolidated net revenues, respectively and 30.8%, 28.4% and 21.4%, respectively, of our Pharmaceuticals Division net revenues. As is customary in the pharmaceutical industry, we accept returns of products we have sold as the products near their expiration date.

Significant research and development projects have a defined cycle, and accordingly, the composition of our customer group in the AAI Development Services and Research and Development Division areas of our business changes from year to year. Because of the project nature of engagements in these business segments, large customers may represent a significant portion of the business in one period but not subsequent periods. We have experienced concentration in these areas of our business in the past, and do not believe that this is unusual for companies which operate in this market. However, we do not believe that revenues from any large customer of the Research and Development Division or AAI Development Services are likely to exceed 10% of our consolidated net revenues in the foreseeable future.

Backlog

Our order backlog consists of anticipated net revenues from signed fee-for-service contracts for which services have not been completed. Once contracted work begins, net revenues are recognized as the service is performed. The order backlog does not include anticipated net revenues for work performed for internal clients or for any variable-priced contracts. During the course of a project, a client may substantially adjust the requested scope of services and corresponding adjustments are made. Our order backlog also includes orders for pharmaceutical products that have been ordered by our customers, but have not yet been shipped.

We believe that our order backlog as of any date is not a meaningful predictor of future results due to the variability and short duration of many of our development services contracts. The backlog can also be affected by adjustments in the scope of contracted projects. At December 31, 2003 and 2002, our order backlog was approximately \$52 million and \$57 million, respectively. We do not expect to fill approximately \$10 million of the 2003 amount by December 31, 2004. Included in the backlog total is \$1.3 million for pharmaceutical products ordered but not yet shipped.

Competition

We compete with companies and organizations in multiple segments of the pharmaceutical industry. The branded drug products of our Pharmaceuticals Division are subject to competition from the branded and

generic products of other pharmaceutical companies, ranging from small specialty pharmaceutical companies to large pharmaceutical companies.

The following tables illustrate the products that compete with the products we sell:

Our Branded Products

<u>Our Products</u>	<u>Competitor's Products</u>
Brethine (tablet)	Volmax Proventil Branded and generic forms of Albuterol sulfate Generic terbutaline sulfate
Brethine (injectable)	Generic terbutaline injectable
Oramorph SR	Avinza Kadian MS Contin generic MS Contin
Roxicodone	generic oxycodone
Darvon/Darvocet	generic propoxyphene
Methadone injection	injectable hydromorphone oxymorphone meperidine

Our Generic Products

<u>Our Products</u>	<u>Competitors' Products</u>
Calcitriol	Calcijex other generic calcitriol products
Azathioprine	Imuran other generic azathioprine products

In addition to the competitive products listed above, additional competitive products may be introduced in the future.

Our AAI Development Services and Research and Development Divisions compete primarily with in-house research, development, quality control, and other support service departments of pharmaceutical and biotechnology companies, as well as university research laboratories and other contract research organizations. We believe that although there are numerous fee-for-service competitors in this industry, there are few competitors that offer the depth or breadth of scientific capabilities that we provide. Some of our competitors, however, may have significantly greater resources than we do. Competitive factors generally include

reliability, turn-around time, reputation for innovative and quality science, capacity to perform numerous required services, financial viability, and price. We believe that we compete favorably in each of these areas.

Government Regulation

The services that we perform and the pharmaceutical products that we develop, manufacture, and sell are subject to various rigorous regulatory requirements designed to ensure the safety, effectiveness, quality and integrity of pharmaceutical products, primarily under the Federal Food, Drug, and Cosmetic Act, including current Good Manufacturing Practice regulations. These regulations are commonly referred to as the cGMP regulations and are administered by the FDA in accordance with current industry standards. Our services and development efforts performed outside the U.S. and products intended to be sold outside the U.S. are also subject to additional foreign regulatory requirements and government agencies.

U.S. laws and federal regulations apply to all phases of investigational and commercial development (i.e. manufacturing, testing, promotion and distribution of drugs, including with respect to our personnel, record keeping, facilities, equipment, control of materials, processes, laboratories, packaging, labeling, storage and advertising). If we fail to comply with these laws and regulations, our drugs, drug improvements, and product line extensions will not be approved by the FDA or will be withdrawn from the market and the data we collect may be out of specification and not acceptable to the FDA requirements, which may result in us not being permitted to market our products. Additionally, we could be subject to significant monetary fines, recalls and seizures of products, closing of our facilities, revocation of drug approvals previously granted to us, and criminal prosecution. Any of these regulatory actions could materially and adversely affect our business, financial condition and results of operations.

To help assure our compliance with applicable laws and regulations, we have quality assurance controls in place at our facilities and we use FDA regulations and guidelines, as well as applicable international standards, as a basis for our quality policies and standard operating procedures. We regularly audit test data, inspect our facilities, and revise our standard operating procedures to meet current cGMPs. In addition, we maintain a system for monitoring product-related complaints for all of our commercial products.

The balance of adhering to FDA compliance while bringing products to market requires us to continuously improve our operating standards in order to reduce the possible risk of FDA actions. In the event of any such action of a material nature, the resulting restrictions on our business could materially and adversely affect our business, financial condition and operating results.

All of our drugs, investigational and commercial, must be manufactured in conformity with International Conference on Harmonization, or ICH, guidances, cGMP regulations and FDA guidances and guidelines. Drug products subject to an approved FDA-application must be manufactured, processed, packaged, held, and labeled in accordance with information contained in the application. Modifications, enhancements, or changes in manufacturing sites of approved products are in many cases subject to additional FDA inspections and supplemental approvals to the existing application. The circumstances requiring inspections and supplemental filings may require a lengthy application process. Our facilities, including the facilities used in our development services business and those of our third-party manufacturers, are periodically subject to inspection by the FDA and other governmental agencies. If such inspections prove unsatisfactory, the operations at these facilities could be interrupted or halted for lengthy periods of time.

Failure to comply with FDA or other governmental regulations can result in warning letters. If those warning letters are not adequately addressed, further actions may lead to fines, unanticipated compliance expenditures, recall or seizure of products or total or partial suspension of production or distribution. For drugs under FDA review, failure to be compliant at manufacturing facilities could stop the FDA's review of our drug approval applications that could, in certain circumstances, extend to the termination of ongoing

research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions, and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have instituted internal compliance programs that consistently comply with cGMPs through strong training and corporate quality oversight, we are cognizant that if these programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could have a material adverse effect on us, our third party manufacturers and our vendors. Most of our vendors are subject to similar regulations and periodic inspections.

Some of our development and testing activities for our customers, and the manufacture, development and testing of our New Pain Products, our Darvon and Darvocet products and our methadone hydrochloride product, are subject to the Controlled Substances Act, administered by the Drug Enforcement Administration, or the DEA, which strictly regulates all narcotic and habit-forming substances. We maintain separate, restricted-access facilities and heightened control procedures for projects involving such substances due to the level of security and other controls required by the DEA.

Our business also involves the controlled storage, use, and disposal of hazardous materials and biological hazardous materials. We are subject to numerous federal, state, local, and foreign environmental regulations governing the use, storage, handling, and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply in all material respects with the standards prescribed by law and regulation in each of our locations, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. We maintain liability insurance for some environmental risks that our management believes to be appropriate and in accordance with industry practice. However, we may not be able to maintain this insurance in the future on acceptable terms. In the event of an accident, we could be held liable for damages that are in excess or outside of the scope of our insurance coverage or that deplete all or a significant portion of our resources.

We are also governed by federal, state and local laws of general applicability, such as laws regulating intellectual property, including patents and trademarks, working conditions, equal employment opportunity, and environmental protection.

In connection with our activities outside the U.S., we also are subject to foreign regulatory requirements governing the testing, approval, manufacture, labeling, marketing, and sale of pharmaceutical products, which requirements vary from country to country. Whether or not FDA approval has been obtained for a product, approval by comparable regulatory authorities of foreign countries must be obtained prior to marketing the product in those countries. For example, some of our foreign operations are subject to regulations by the European Medicines Evaluations Agency and the U.K. Medicines Control Agency. The approval process may be more or less rigorous from country to country, and the time required for approval may be longer or shorter than that required in the U.S. Therefore pharmaceutical product approval and policies for pricing required for marketing will vary from country to country due to different regulations and policies required by each.

The Drug Development Regulatory Process

New Drug Approval Process. FDA approval is required before any new drug can be marketed and sold in the U.S. This approval is obtained through the new drug application, or NDA, process, which involves the submission to the FDA of complete pre-clinical data about new compounds and their characteristics, clinical data obtained from studies in humans showing the safety and effectiveness of the drug for the proposed therapeutic use, and chemistry, manufacturing, and controls data documenting how the drug is made and manufacturing operations are controlled.

Before introducing a new drug into humans, stringent government requirements for pre-clinical data must be satisfied. The pre-clinical data is obtained from laboratory studies, and tests performed on animals, which

are submitted to the FDA in an investigational new drug application, or an IND. The pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials of the new drug in humans. Pursuant to the IND, the new drug is tested in humans for safety, adverse effects, dosage, tolerance absorption, metabolism, excretion and other elements of clinical pharmacology, and for effectiveness for the proposed therapeutic use.

Clinical trials are conducted in three sequential phases (i.e., Phase I, Phase II, and Phase III). The clinical development plan, or the process of completing clinical trials during the investigational period, for a new drug may take several years and require the expenditure of substantial operational and financial resources. Phase I clinical trials frequently begin with the initial introduction of the investigational drug product into healthy humans and test primarily for safety. Phase II clinical trials typically involve a small sample of the intended patient population to assess the efficacy of the investigational drug product for a specific indication, to determine dose tolerance and the optimal dose range and to gather additional information relating to safety and potential adverse effects. Phase III clinical trials are studies with a statistically qualified larger study population that compares the active drug product against a placebo. These studies, conducted in a randomized group where the drug and placebo are typically blinded from the physician and patient, further evaluate clinical safety and efficacy at different study sites to determine the overall risk-benefit ratio of the drug and provide an adequate basis for product labeling.

Each clinical trial is conducted in accordance with rules, or protocols, that are developed to detail the objectives of the study, including methods to monitor safety and efficacy and the precise criteria to be evaluated. These protocols must be submitted to the FDA as part of the IND. In some cases, the FDA allows a company to rely on data developed in foreign countries, or previously published data, which eliminates the need to independently repeat some or all of the studies.

Once sufficient data have been developed pursuant to the IND, the NDA is submitted to the FDA to request approval to market the new drug. Preparing an NDA involves substantial data collection, verification and analysis, and expense, and there is no assurance that FDA approval of an NDA can be obtained on a timely basis, if at all. The approval process is affected by a number of factors, primarily the risks and benefits demonstrated in clinical trials as well as the severity of the disease and the availability of alternative treatments. The FDA might not approve an NDA if the regulatory criteria are not satisfied or, alternatively, may require additional studies to enhance the overall risk-benefit ratio prior to an approval action.

Referencing and Relying on New Drug Applications. With respect to the branded pharmaceutical products (e.g., Darvon and Darvocet) that we have acquired, we are often able to reference the original NDA along with the marketing rights to the products. As a result, when improving these products or developing product line extensions, we are permitted to file a supplemental NDA, or a new drug application known as a 505(b)(2) NDA, that directly cross references all of the data in the original application. This provision in the federal Food, Drug, and Cosmetic Act allows us to shorten our development process for improvements and line extensions. For example, we may be able to reduce the number of clinical trials in a clinical development plan with less extensive, less time-consuming, and less costly Phase II and Phase III testing, with respect to any new products that we may select to develop.

Similarly, a 505(b)(2) application allows us to cross reference NDAs, or information therein, that we do not own and are not authorized to reference directly. The 505(b)(2) NDA may, in certain cases, permit us to meet NDA approval requirements with less original scientific data than would normally be required, and may allow us to begin drug development in a later phase, so as to reduce the time and expense involved in any particular phase, for any new products we select to develop. Applications under 505(b)(2) are subject to certain patent and non-patent exclusivity rights applicable to the NDAs on which they rely, if such rights remain in effect when such applications are submitted. If we are unable to proceed with anticipated 505(b)(2) applications for any of the products that we are developing, our FDA approval costs will increase.

Abbreviated New Drug Application Process for Generic Products. A generic drug contains the same active ingredient as a specified brand name drug and usually can be substituted for the brand name drug by the pharmacist. FDA approval is required before a generic drug can be marketed. Approval of a generic drug is obtained through the filing of an abbreviated new drug application, or an ANDA, under section 505(j) of the Food, Drug, and Cosmetic Act. Submission and approval of an ANDA is subject to certain patent and non-patent exclusivity rights applicable to the brand name drug, if such rights remain in effect when the ANDA is submitted. When processing an ANDA, the FDA waives the requirement of conducting full clinical studies provided that the drug is proven bioequivalent to the reference listed drug (i.e., usually the applicant of the NDA) in a Phase I study conducted in a small number of healthy volunteers. Bioavailability relates to the rate and extent of absorption and levels of concentration of a drug active ingredient in the blood stream needed to produce a therapeutic effect. Bioequivalence compares the bioavailability of one drug with another that contains the same active ingredient, and when established, indicates that the rate and extent of absorption and levels of concentration of a generic drug in the body are the same as the previously approved brand name drug. An ANDA may be submitted for a drug on the basis that it is the equivalent to a previously approved drug or, in the case of a new dosage form or other close variant, is suitable for use under the conditions specified.

The timing of final FDA approval of ANDAs depends on a variety of factors, including whether the applicant challenges any listed patents for the brand-name drug and whether the brand-name manufacturer is entitled to one or more non-patent statutory exclusivity periods, during which the FDA is prohibited from accepting or approving applications for generic drugs.

Under section 505(j), the FDA may impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the generic drug approval process. In some situations, the FDA is required not to accept or review ANDAs for a period of up to three years from a company or an individual that has committed certain violations. The FDA may temporarily deny approval of ANDAs during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, suspend the marketing of approved generic drugs by the affected company. The FDA also may impose civil penalties and withdraw previously approved ANDAs. Neither we nor any of our employees have ever been the subject of debarment procedures.

Manufacturing Requirements. Before approving a drug, the FDA also requires that our procedures and operations conform to cGMP regulations, ICH guidances and manufacturing guidelines and guidances published by FDA. We must be in compliance with all of the regulatory and quality regulations at all times during the manufacture of our products. To help insure compliance with the regulatory and quality regulations, we must continue to spend time, money, and effort in the areas of production and quality control to ensure full technical compliance. If the FDA believes a company is not in compliance with its regulations, it may withhold new drug approvals, as well as approvals for supplemental changes to existing approvals, preventing the company from exporting its products. It may also classify the company as an unacceptable supplier, thereby disqualifying the company from selling products to federal agencies. We believe we are currently in compliance with the cGMP regulations.

Post-approval Requirements. After initial FDA approval for the marketing of a drug has been obtained, further studies, including Phase IV studies, typically regarded as post-marketing studies, may be required to provide additional data on safety or effectiveness. Also, the FDA requires post-marketing reporting to monitor the adverse effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the drug. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, or manufacturing facility, a supplemental application seeking approval of the modifications must be submitted to the FDA or other regulatory authority. Prospectively, the FDA regulates

our post-approval promotional labeling and advertising activities to assure that such activities are being conducted in conformity with statutory and regulatory requirements.

Health Care Fraud and Abuse Laws

Federal and state health care fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include antikickback statutes and false claims statutes. The federal health care program antikickback statute makes it illegal for anyone to knowingly and willfully make or receive "kickbacks" in return for any health care item or service reimbursed under any federally financed healthcare program. This statute applies to arrangements between pharmaceutical companies and the persons to whom they market, promote, sell, and distribute their products. In 2003, the Office of the Inspector General of the Department of Health and Human Services issued a "Compliance Program Guidance for Pharmaceutical Manufacturers" describing pharmaceutical companies' activities that may violate the statute. There are a number of exemptions and safe harbors protecting certain common marketing activities from prosecution. These include exemptions or safe harbors for product discounts, payments to employees, personal services contracts, warranties, and administrative fees paid to group purchasing organizations. These exemptions and safe harbors, however, are drawn narrowly.

Federal false claims laws prohibit any person from knowingly making a false claim to the federal government for payment. Recently, several pharmaceutical companies have been investigated or prosecuted under these laws, even though they did not submit claims to government healthcare programs. The prosecutors alleged that they were inflating drug prices they report to pricing services, which are in turn used by the government to set Medicare and Medicaid reimbursement rates. Pharmaceutical companies also have been prosecuted under these laws for allegedly providing free products to customers with the expectation that the customers would seek reimbursement under federal programs for the products.

Additionally, the majority of states have laws similar to the federal antikickback law and false claims laws. Sanctions under these federal and state laws include monetary penalties, exclusion from reimbursement for products under government programs, criminal fines and imprisonment.

We have internal policies and practices requiring and detailing compliance with the health care fraud and abuse laws and false claims laws. Because of the breadth of these laws and the narrowness of the safe harbors, however, it is possible that some of our business practices could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

Employees

At December 31, 2003, we had approximately 1,300 full-time equivalent employees, of which 95 hold Ph.D. or M.D. degrees, or the foreign equivalent. We believe that our relations with our employees are good. None of our employees in the U.S. are represented by a union. European laws provide certain representative rights to our employees in those jurisdictions.

Our continued performance depends on our ability to attract and retain qualified professional, scientific, and technical staff. The level of competition among employers for these skilled personnel is high. We believe that our employee benefit plans enhance employee morale, professional commitment and work productivity and provide an incentive for employees to remain with aaiPharma. We have experienced difficulty in attracting and retaining qualified staff for certain positions in our Phase II and III operations, where high turnover is an industry-wide problem. It is possible that as competition for skilled employees increases at our other operations or locations, we could experience similar problems there as well.

Intellectual Property

Our ability to successfully commercialize new branded products or technologies is significantly enhanced by our ability to secure strong intellectual property rights — generally patents — covering these products and technologies and to avoid infringement of valid third-party patents. We intend to seek patent protection in the United States and selected foreign countries and to vigorously prosecute patent infringements, as we deem appropriate. We currently own patents issued by the U.S. Patent and Trademark Office, and have additional patent applications filed and pending with the U.S. Patent and Trademark Office. Additionally, we have assigned or transferred an additional six of our patents to third parties for value.

Our patents cover proprietary processes and techniques, or formulation technologies, that may be applied to both new and existing products and chemical compounds. Our patents also cover new chemical entities or compounds, pharmaceutical formulations, and methods of using certain compounds. We also seek to patent new physical and chemical characteristics of known compounds, and previously unknown compounds.

We are aggressively pursuing patent infringement against Schwarz Pharma AG and related companies to protect our rights under two of our patents with respect to omeprazole. During the first sixteen months of sales, the defendants in this action received over \$1.1 billion in sales from the product we believe is infringing our patent. The case is currently scheduled for trial in June 2005. Litigation involves a high degree of uncertainty as to outcomes and we cannot predict the outcome of our infringement claims. The defendants have also asserted various counter claims against us, including violations of antitrust laws. See “Item 3. Legal Proceedings – Patent Litigation” for more information on this proceeding.

We have a license in the U.S. and some other countries to use the patents, patent applications, and know-how associated with certain pharmaceutical formulation technologies for mutually acceptable drug candidates. The ProSLO and ProSLO II technologies are licensed from Osmotica Corporation. Like our own formulation technologies mentioned above, these technologies may be used to develop mutually acceptable new drug products or improve the characteristics of mutually acceptable existing products and compounds.

In addition to our patents, we rely upon trade secrets and unpatented proprietary know-how where we believe the public disclosures would not be in our best strategic interest. We seek to protect these assets as permitted under state or federal law and by requiring our employees, consultants, licensees, and other companies to enter into confidentiality and nondisclosure agreements and, when appropriate, assignment of invention agreements.

In the case of strategic partnerships or collaborative arrangements requiring the sharing of data, our policy is to disclose to our partner only such data as is relevant to the partnership or as required under the arrangement during its term and so long as our partner agrees to keep those duties confidential.

Item 2. Properties

Our principal executive offices are located in Wilmington, North Carolina, in a 73,000-square foot owned facility. Our primary U.S. facilities are located in Wilmington, North Carolina; Research Triangle Park, North Carolina; North Brunswick, New Jersey; Natick, Massachusetts; Charleston, South Carolina; and Shawnee, Kansas. These facilities provide approximately 433,000 square feet of total operational and administrative space. Our primary European facilities are located in Neu-Ulm, Germany and include approximately 112,400 square feet of operational and administrative space. We also have U.S. sales representatives based throughout the United States and foreign sales representatives based in Italy, Japan, Sweden, Germany and the U.K. We believe that our facilities are adequate for our current operations and that suitable additional space will be available when needed.

Primary Operating Facilities

<u>Location</u>	<u>Primary Use</u>	<u>Approximate Square Footage</u>	<u>Leased/Owned</u>
Wilmington, N.C.	Corporate Headquarters	73,000	Owned
Wilmington, N.C.	Manufacturing/Warehouse/ Office	45,200	Owned
Wilmington, N.C.	Laboratory/Office	20,000	Leased; lease expires October 2006
Wilmington, N.C.	Laboratory/Office	33,000	Owned
Wilmington, N.C.	Clinical Distribution Warehouse and Storage for Stability Studies	25,600	Leased; lease expires September 2008
Chapel Hill, N.C.	Laboratory/Clinic	31,000	Owned
North Brunswick, N.J.	Laboratory/Office/Warehouse	74,600	Leased; lease expires August 2010
Shawnee, Kansas	Laboratory/Office/Warehouse	31,500	Leased; lease expires December 2005
Natick, Mass.	Office	44,800	Leased; lease expires March 2007
Charleston, S.C.	Sterile Manufacturing/Office	48,000	Leased; lease expires July 2011
Neu-Ulm, Germany	European Headquarters/ Laboratory/Clinic	112,400	Leased; lease expires December 2008

Item 3. Legal Proceedings

We are party to lawsuits and administrative proceedings incidental to the normal course of our business. Our material legal proceedings are described below. We cannot predict the outcomes of these matters. However, except as noted below, we do not believe that any liabilities related to such lawsuits or proceedings will have a material adverse effect on our consolidated financial condition, results of operations or cash flows. Prosecuting and defending these material legal proceedings, including responding to governmental inquiries, has resulted, and is expected to continue to result, in a significant diversion of management's attention and resources and an increase in professional fees.

Government Investigations

On August 7, 2003 we received a letter from the staff of the Enforcement Division of the SEC (the "Enforcement Division") requesting voluntary production of certain documents. We responded to this letter on August 21, 2003 and supplemented our response on August 29, 2003.

Independent of the August 7, 2003 inquiry letter, on September 26, 2003, certain members of our board and management voluntarily met with, and provided documents to, the staff of the Enforcement Division. As a follow-up to this September 26, 2003 meeting and as part of the inquiry initiated on August 7, 2003, on October 8, 2003, we received a further request from staff of the Enforcement Division for voluntary production of certain documents, to which we responded on October 30, 2003.

On January 14, 2004 and April 26, 2004, we received letters from the SEC's Division of Corporate Finance commenting on, asking questions about, and seeking additional disclosure with respect to certain of our periodic reports. We have responded to these letters.

In April 2004, in connection with an investigation conducted by the United States Attorneys Office for the Western District of North Carolina (the "U.S. Attorneys Office"), we received five federal grand jury subpoenas for document production and potential testimony related to, among other things, certain transactions regarding our 2002 and 2003 financial information, the terms, conditions of employment and compensation arrangements of certain of our senior management personnel, compensation and incentive arrangements for employees responsible for the sale of our Brethine, Darvocet, calcitriol, azathioprine and Darvon Compound products, quantities of the foregoing products in distribution channels, financial benefits with respect to specified corporate transactions to our senior management and others, certain loans obtained by us, extensions of credit, if any, by us to officers or directors, accounting for sales and returns of our foregoing products, our analysts' conference calls on financial results, internal and external investigations of pharmaceutical product sales activities, and related matters. We have also been advised that the SEC has initiated an inquiry into at least the same issues investigated by the Special Committee. The U.S. Attorneys Office has advised that we may also receive a subpoena from the SEC.

We and the Special Committee have agreed to cooperate fully with the government investigations, and the Special Committee has agreed to share all results of its investigation with the SEC and the U.S. Attorneys Office. To that end, two meetings of our outside counsel with attorneys for the U.S. Attorneys Office and the SEC have taken place and numerous documents as requested by these government agencies have been voluntarily produced. We are attempting to schedule a third meeting with the U.S. Attorneys Office and the SEC in July in order to provide additional information related to the Special Committee's investigation to these government agencies. We and the Special Committee intend to facilitate any interviews of our employees or officers that may be requested by these government agencies.

The Department of Justice, SEC and other government agencies that are investigating or might commence an investigation of aaiPharma could impose, based on a claim of fraud, material misstatements, violation of false claims law or otherwise, civil and/or criminal sanctions, including fines, penalties, and/or administrative remedies. If any government sanctions are imposed, which we cannot predict or reasonably estimate at this time, our business, financial condition, results of operations or cash flows could be materially adversely affected. These matters have resulted, and are expected to continue to result, in a significant diversion of management's attention and resources and in significant professional fees.

On January 2, 2004, we received separate letters from the Kentucky Office of Attorney General and the Florida Office of Attorney General advising that each was currently investigating allegations regarding our pricing practices related to our average manufacturer price and best price calculations that are used by the government to set Medicaid reimbursement rates. Neither letter requested that we provide any information, and each letter merely requested that we retain all documents with respect to these calculations pursuant to a newly adopted federal regulation that would have permitted the destruction of these documents three years after the applicable prices were reported, except to the extent we were aware of an ongoing investigation. It is our understanding that many other pharmaceutical companies received similar letters at that time from attorneys general in a number of states and that such letters may have been in response to the new federal regulation that would have otherwise allowed the destruction of documents reflecting these pricing calculations. A number of attorneys general, including the Florida and Kentucky attorneys general,

petitioned the U.S. Secretary of Health and Human Services to withdraw the new regulation. We are not aware of any further developments in these investigations.

Federal Securities and ERISA Litigation

We and certain of our current and former officers have been named as defendants in purported shareholder class action lawsuits alleging violations of federal securities laws. These lawsuits were filed beginning in February 2004 and are pending in the U.S. District Court for the Eastern District of North Carolina. These lawsuits assert claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of our common stock during the period from January 31, 2002 through and including March 1, 2004 (the "Class Period"). The complaints allege generally that the defendants knowingly or recklessly made false or misleading statements during the Class Period concerning our financial condition and that our financial statements did not present our true financial condition and were not prepared in accordance with generally accepted accounting principles. The complaints seek certification as a class action, unspecified compensatory damages, attorneys' fees and costs, and other relief. By order dated April 16, 2004, the district court consolidated the securities lawsuits into one consolidated action. We expect that the plaintiffs will file a consolidated, amended complaint later in 2004, to which we will respond in lieu of responding to the individual complaints.

In addition, we, one of our former officers, certain of our employees and others have been named in a purported class action brought by an aaiPharma retirement plan participant and beneficiary asserting claims under the Employee Retirement Income Security Act of 1974, as amended ("ERISA") on behalf of a class of all persons who are or were participants or beneficiaries of the aaiPharma Inc. Retirement and Savings Plan (the "Plan") during the period from April 24, 2002 to March 31, 2004. The complaint alleges generally that the defendants breached fiduciary duties owed under ERISA with respect to the investment of Plan assets in aaiPharma stock by misleading participants and beneficiaries of the Plan regarding our earnings, prospects, and business condition. The complaint seeks certification as a class action, unspecified compensatory damages, attorneys' fees and costs, and other relief. This ERISA lawsuit is pending in U.S. District Court for the Eastern District of North Carolina.

These securities and ERISA lawsuits are at an early stage, and no lead plaintiff has yet been appointed, nor a consolidated amended complaint served, in the federal securities litigation. We are not required to file an answer or motion to dismiss in the federal lawsuits until after service of the consolidated amended complaint on us and no discovery has yet occurred in these lawsuits. By, and subject to, the terms of our bylaws, we have certain obligations to indemnify the current and former officers and employees of the Company who have been named as defendants in these lawsuits. We have purchased directors and officers liability insurance ("D&O insurance") that may provide coverage for some or all of these lawsuits and governmental investigations. There is a risk, however, that some or all of the claims or expenses will not be covered by such policies; or that, even if covered, our ultimate liability will exceed the available insurance. Although we intend to vigorously pursue all defenses available in these lawsuits, an adverse determination in these lawsuits or an inability to obtain payment under our D&O insurance policies for litigation and indemnification costs and any damages ultimately borne by us as a result of these lawsuits and investigations could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Patent Litigation

We are a party to a number of legal actions with generic drug companies. We are involved in four lawsuits centered on our omeprazole-related patents, including one lawsuit brought by us against an alleged infringer of our patents and three lawsuits which were brought by third parties against us and are currently essentially inactive. Omeprazole is the active ingredient found in Prilosec, a drug sold by AstraZeneca.

Two omeprazole-related cases have been filed against us by Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. in the U.S. District Court for the Southern District of New York in July 2001 and November 2001. The plaintiffs in these cases have challenged the validity of five patents that we have obtained relating to omeprazole and are seeking a declaratory judgment that their generic form of Prilosec does not infringe these patents. Additionally, they have alleged misappropriation of trade secrets, tortious interference, unfair competition and violations of the North Carolina Unfair Trade Practice Act. We have denied the substantive allegations made in these cases.

Both of these cases against us are in early stages of litigation. However, while these plaintiffs have sought approval from the FDA to market a generic form of Prilosec, no such FDA approval has, as of March 14, 2004, been granted to them. In addition, these plaintiffs' omeprazole product has been found in separate litigation to infringe certain patents of AstraZeneca and the infringement findings have been upheld on appeal. These lawsuits are essentially inactive at this time. Only limited discovery has occurred in these lawsuits and no additional discovery is currently being sought. No date has been set for trial. In the event that these lawsuits again become active, we intend to vigorously defend the patents' validity and to determine whether or not Dr. Reddy's product infringes any of our relevant patents.

The third case involving our omeprazole patents was brought against us in August 2001 by Andrx Pharmaceuticals, Inc. in the U.S. District Court for the Southern District of New York. Andrx has challenged the validity of three of our omeprazole patents and has also sought a declaratory judgment that its generic omeprazole product does not infringe these patents. Furthermore, Andrx claims violations of federal and state antitrust laws with respect to the licensing of these omeprazole patents and has sought injunctive relief and unspecified treble damages. We have denied the substantive allegations made by Andrx.

This case is in an early stage of litigation. While Andrx has received FDA approval for its generic omeprazole product, to our knowledge, it is not currently marketing this drug in the U.S. following a judicial finding that Andrx's omeprazole product infringed certain AstraZeneca patents, which findings have been upheld on appeal. No date has been set for trial. No discovery is currently being sought. We have filed a motion to dismiss the litigation on various grounds and Andrx has objected to our motion. The lawsuit is essentially inactive at this time. As of June 1, 2004, the judge has not decided our motion to dismiss the litigation.

The fourth case involving our omeprazole patents was brought in December 2002 by us against Kremers Urban Development Co., Schwarz Pharma Inc. and Schwarz Pharma AG (collectively, together with the other named defendants, "KUDCO") in the U.S. District Court for the Southern District of New York. KUDCO has a generic omeprazole product with final FDA marketing approval, was found not to infringe the AstraZeneca patents in the separate AstraZeneca patent litigation, and is currently selling its generic substitute for Prilosec in the U.S. marketplace.

We initially brought the lawsuit under our U.S. Patent No. 6,268,385. Following the collection of additional information concerning KUDCO's commercially marketed product, we sought leave of the court to file an amended complaint, adding additional claims of infringement and contributory infringement under our U.S. Patent No. 6,326,384 and joining as defendants Schwarz Pharma Manufacturing Inc. and Schwarz Pharma USA Holdings Inc. These two patents include, among other claims, claims directed to compositions and methods wherein certain characteristics of solid state omeprazole are essentially the same in formulated drug product as in its active ingredient.

In September 2003, the judge granted us leave to file the first amended complaint adding our second patent and the additional KUDCO affiliates to the lawsuit. Following initial discovery, we sought leave of the court to file a second amended complaint, adding Kremers Urban Inc., another KUDCO affiliate, to the

lawsuit. On February 26, 2004, the judge granted us leave to file the second amended complaint, adding Kremers Urban Inc. to the lawsuit.

KUDCO has filed its answer to our complaint, denying our claims, asserting various affirmative defenses to our claims, and asserting counterclaims of patent invalidity, product non-infringement and antitrust violations under federal and state antitrust laws. KUDCO is also contesting the personal jurisdiction of the court over all of the defendants in this lawsuit other than Kremers Urban Development Co., Kremers Urban Inc. and Schwarz Pharma Inc. Motions on the jurisdictional issues are pending before the court. We have denied the substantive allegations made by KUDCO in its counterclaims.

Substantial discovery of both sides' documents and of defendants' product samples has occurred in the lawsuit, although both sides asserted numerous discovery deficiencies against the other in the lawsuit. On February 26, 2004, the judge assigned the discovery disputes to a federal magistrate for resolution. Discovery is continuing at this time. The parties previously had agreed to the commencement of the trial in January 2005 but have recently moved the trial date to June 2005.

We have previously indicated to KUDCO a willingness to grant a license under our omeprazole patents for an appropriate royalty.

In the absence of KUDCO taking a royalty-bearing license, we are seeking damages equal to a reasonable royalty on all infringing sales by the KUDCO defendants since commercial launch of their generic substitute for Prilosec on December 9, 2002 through the date of a judicial decision in the litigation, and a permanent injunction on subsequent sales thereafter (unless KUDCO takes a license), among other remedies, in the event that we ultimately prevail in the litigation. The KUDCO defendants have publicly confirmed sales of their generic omeprazole product during the first sixteen months after launch of their product of approximately \$1.1 billion. In the absence of a license, we intend to vigorously prosecute the case, defend our patent rights and defend against the foregoing defenses and counterclaims asserted by KUDCO. It is possible that the omeprazole-related patents subject to the foregoing four lawsuits will be found invalid, unenforceable or not infringed and, while currently stayed by the judge in the KUDCO litigation, it is possible that the defendants' antitrust counterclaims will ultimately be allowed to proceed and be litigated and, if adversely found, a material adverse effect on our consolidated financial statements, results of operations or cash flow could result.

In cases where we have initiated an action, we intend to prosecute our claims to the full extent of our rights under the law. In cases where we are named defendants, we intend to vigorously pursue all defenses available.

Contract Sales Force Litigation

On April 15, 2004, we filed a lawsuit against Athlon Pharmaceuticals, Inc. seeking a declaratory judgment that we were entitled to terminate the Service Agreement (the "Athlon Service Agreement") dated July 16, 2003, as amended, between us and Athlon as well as damages and injunctive relief for material breaches of the Athlon Service Agreement by Athlon. The Athlon Service Agreement incorporated the terms and conditions pursuant to which representatives of Athlon would promote the sale of our Darvocet A500 product to physicians. We initially paid Athlon \$3,350,000 to build its sales force to promote the sale of our Darvocet A500, and the terms of the Athlon Service Agreement would require us to pay Athlon an additional \$1,200,000 each month for such services for the contract period of 36 months, commencing in October 2003, subject to Athlon's compliance with certain representations, warranties and covenants, some of which are described below.

The lawsuit asserts that Athlon has materially breached the Athlon Service Agreement in several ways, including failure to: (i) provide the required number of sales representatives during our launch of Darvocet

A500 commencing in October 2003, (ii) use its best efforts to promote Darvocet A500 at the targeted levels of first and second pharmaceutical details to physicians, (iii) perform the services to the best of its ability, as contractually required, and (iv) require its sales representatives to perform the contracted services, as required, in a professional manner consistent with industry standards and in conformance with that level of care and skill ordinarily exercised by professional contract sales organizations in similar circumstances. The lawsuit also asserts that Athlon breached its representation and warranty that it would perform, and would require its sales representatives to perform, the contracted services in substantially the same manner that it would promote Athlon's own products.

Athlon has asserted several counterclaims, including breach of an implied covenant of good faith in fair dealing and anticipatory breach of the contract. We have filed a reply denying these allegations.

On June 4, 2004, we sent a notice of termination of the Athlon Service Agreement to Athlon. We also informed Athlon of our intent to amend the lawsuit to assert the defense of fraud in the inducement in the formation of the agreement on the part of Athlon and other claims.

We intend to prosecute our claims, and defend against the counterclaims made by Athlon in connection with the referenced lawsuit or related litigation, to the full extent permitted by law.

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

No matters were submitted to our stockholders during the fourth quarter of 2003.

PART II

Item 5. Market for the Registrant's Common Equity and Related Stockholder Matters

The price range of the our common stock, which is traded on the NASDAQ National Market under the symbol "AAII," is listed below by quarter for the years ended December 31, 2003 and 2002:

	<u>Quarter</u>			
	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>
2003:				
High	\$21.90	\$20.10	\$22.22	\$25.85
Low	\$ 8.15	\$ 8.62	\$15.99	\$16.68
2002:				
High	\$23.96	\$25.35	\$14.36	\$11.51
Low	\$14.09	\$11.73	\$ 7.68	\$ 6.54

The foregoing prices have been adjusted for the three-for-two common stock split, effected through a stock dividend, paid on March 10, 2003.

We estimate there were approximately 5,450 holders of record for our common stock as of March 31, 2004. No cash dividends were declared during 2003 or 2002, and our senior secured credit facilities prohibit us from paying cash dividends.

We received notice on March 30, 2004 from the NASDAQ National Market that, due to the delay in filing of our Form 10-K for the fiscal year ended December 31, 2003, we were not in compliance with certain NASDAQ marketplace rules and that our common stock would be subject to delisting at the opening of business on April 8, 2004, unless we requested a hearing pursuant to NASDAQ rules. We requested and participated in a hearing before a NASDAQ listing qualifications panel on April 29, 2004 in which we committed to filing this Report on Form 10-K on or before June 15, 2004 and to file amended quarterly reports on Form 10-Q for each of the three quarters of 2003, and our quarterly report on Form 10-Q for the period ended March 31, 2004, on or before June 30, 2004. We have not received notification of the outcome of the delisting hearing. On May 18, 2004, we received notice from the NASDAQ National Market that we were delinquent in the filing of our Form 10-Q for the period ended March 31, 2004.

Item 6. Selected Consolidated Financial Data.

The selected historical financial data set forth below are not necessarily indicative of the results of future operations and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes and other financial information appearing elsewhere in this report.

SELECTED FINANCIAL DATA

	Years Ended December 31,				
	2003	2002 (as restated)	2001	2000	1999
	(in thousands, except per share amounts)				
Statement of Operations Data:					
Net revenues	\$ 224,977	\$ 230,510	\$ 141,073	\$ 104,245	\$ 102,175
Direct costs (excluding depreciation and royalty expense)	114,837	90,697	67,197	47,642	52,611
Selling	39,534	23,077	13,749	11,652	11,945
General and administrative	40,463	40,109	26,538	23,773	21,992
Research and development	21,788	20,853	10,482	11,891	10,760
Depreciation	7,973	7,156	7,755	7,253	7,249
Royalty expense	1,095	-	-	-	-
Intangible asset impairment	20,600	-	-	-	-
Direct pharmaceutical start-up costs	-	-	2,123	-	-
Transaction, integration and restructuring costs (1)	-	-	-	-	6,400
Income (loss) from operations	(21,313)	48,618	13,229	2,034	(8,782)
Other expense, net	(15,892)	(26,958)	(4,090)	(1,916)	(1,409)
Income (loss) before income taxes and cumulative effect of accounting change	(37,205)	21,660	9,139	118	(10,191)
Provision for (benefit from) income Taxes	(4,502)	8,542	3,199	(441)	(2,278)
Income (loss) before cumulative effect of accounting change	(32,703)	13,118	5,940	559	(7,913)
Cumulative effect of a change in accounting principle, net of a tax benefit of \$495	-	-	-	(961)	-
Net income (loss)	\$ (32,703)	\$ 13,118	\$ 5,940	\$ (402)	\$ (7,913)
Basic earnings (loss) per share (2)	\$ (1.18)	\$ 0.48	\$ 0.22	\$ (0.02)	\$ (0.31)
Weighted average shares outstanding	27,730	27,348	26,691	26,232	25,806
Diluted earnings (loss) per share (2)	\$ (1.18)	\$ 0.46	\$ 0.22	\$ (0.02)	\$ (0.31)
Weighted average shares outstanding	27,730	28,359	27,462	26,657	25,806

As of December 31,

	2003	2002 (as restated)	2001	2000	1999
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	\$ 8,785	\$ 6,532	\$ 6,371	\$ 1,225	\$ 1,988
Working capital	(12,960)	15,357	20,493	10,558	6,507
Property and equipment, net	57,236	53,125	37,035	42,161	45,026
Total assets	534,597	433,502	196,286	112,151	123,558
Long-term debt, less current portion	338,844	277,899	78,878	509	962
Redeemable warrants	-	-	2,855	-	-
Total stockholders' equity	74,723	95,254	76,364	65,721	66,558

- (1) In connection with our merger with Medical & Technical Research Associates, Inc., we recorded a \$6.4 million unusual item in 1999.
- (2) All share and per share amounts have been restated to reflect the March 2003 three-for-two stock split for each period presented as if it had occurred at the beginning of the period.

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

The Company is restating its financial statements for the first, second and third quarters of both 2002 and 2003 and for the year 2002 (the "Restatement"). The Restatement is reported in this Annual Report on Form 10-K for the year ended December 31, 2003 and will be reported in amendments to our Quarterly Reports on Form 10-Q for the periods ended March 31, 2003, June 30, 2003 and September 30, 2003.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this report. The notes to our consolidated financial statements set forth our critical accounting policies, including policies relating to revenue recognition, intangible assets, inventories and income taxes. These policies are summarized below under "Critical Accounting Policies."

Overview

We are a science-based specialty pharmaceutical company with over twenty-four years' experience in drug development. In 2003 and 2002, the majority of our net revenues were from our product sales and product development businesses. Prior to 2002, the majority of our net revenues were in our development services business. Major customers for our pharmaceutical products are large, well-established medical wholesalers and distributors. Major customers for our development services and product development businesses are pharmaceutical and biotechnology companies.

On January 30, 2003, our Board of Directors approved a three-for-two stock split of our common shares. On March 10, 2003, each stockholder received one additional share of common stock for every two shares they owned on the record date of February 19, 2003. All share and per share amounts have been restated to reflect the stock split for each period presented as if it had occurred at the beginning of the period.

Pharmaceuticals Division – Our Product Sales Business

Our product sales business unit commercializes pharmaceutical products in our targeted therapeutic classes. We are focused on acquiring established, branded pharmaceutical products, developing improved products and product line extensions, and marketing and promoting these products. We currently market products under our various brand names as well as certain generic products. In 2003, we began selling the following products:

<u>Product</u>	<u>Month</u>
Calcitriol	March
Azathioprine	March
Darvocet A500	September
Roxicodone	December
Oramorph SR	December
Roxanol	December
Duraclon	December

The principal costs of this business include manufacturing costs, either internally or under agreements with third-party manufacturers, selling expense of our sales force, payments in connection with a contract sales force and general and administrative costs of our business unit management team. Our product sales business unit also includes the commercial manufacturing of low volume products marketed and sold by other pharmaceutical companies. During 2003, net revenues from product sales were \$122.0 million, or 54% of our consolidated net revenues.

Our results of operations can be influenced by the timing of purchases made by our customers and the magnitude of the inventories of our products that our customers desire to maintain. These customers are wholesalers and may increase their purchases if they anticipate a price increase. Wholesalers may anticipate a price increase due to the timing of prior increases, the acquisition of a product by a new supplier or other reasons. Any increase in revenues during one period due to an anticipated price increase may likely be offset by decreased revenues in subsequent periods. Thus, as described in more detail below, there may be some volatility of our pharmaceutical product revenues in future periods due to the timing of our customers' purchasing decisions.

AAI Development Services – Our Development Services Business

Our development services business unit, AAI Development Services, provides a comprehensive range of development services through two primary groups, a non-clinical group and a clinical group. The non-clinical group analyzes and tests various chemical compounds and provides small scale manufacturing of chemical compounds to be used for human clinical trials. The services performed by the non-clinical group also include chemical analysis, chemical synthesis, drug formulation, bio-analytical testing, product life cycle management studies, and regulatory and compliance consulting. All of these non-clinical services involve either laboratory work or consulting services. The clinical group performs testing for customers of new pharmaceutical products in humans under controlled conditions as part of the regulatory approval process for pharmaceutical products. These clinical services involve conducting human clinical studies and the statistical analysis relating to these studies.

Both the non-clinical and clinical groups receive requests for services from customers, often on a competitive basis. These projects vary in length from one month to several years. In general, our customers may cancel a project upon 30 days' notice. The principal expenses of this business are labor costs, including employee benefits, and equipment and facility-related costs. During 2003, net revenues of our development services business unit were \$86.5 million, or 38% of our consolidated net revenues.

Research and Development Division – Our Product Development Business

Our product development business unit, our Research and Development Division, uses our research and development expertise and capabilities to enhance and develop new drug-delivery technologies and improve existing pharmaceutical products. We also apply this expertise to internally develop our own new products and improve our acquired products. We license the developed technologies and products to customers, usually before the development is complete. We generally receive payments for our efforts and innovations upon the occurrence of defined events, known as milestones, which are intended to help cover the costs of development. These milestone payments are not refundable. In most cases, we also receive royalties on the eventual sales of the product. Because of the long-term nature of these projects, we may recognize revenues from milestone payments or royalties in one period and the associated expenses in prior periods. The principal expense of this business is research and development expense, which consists primarily of labor costs, raw material expenses, third-party consulting and testing costs and costs for clinical trials. In some cases, these costs may be directly reimbursed by our customers. During 2003, net revenues of our product development business unit were \$16.5 million, or 7% of our consolidated net revenues.

Product Acquisitions

Roxicodone, Oramorph SR, Roxanol and Duraclon Product Lines. On December 2, 2003, we acquired a line of pain management products, which treat moderate-to-severe pain, (the "New Pain Products") and existing inventory from subsidiaries of Elan Corporation, plc. in an asset purchase. We acquired these product lines and related intangible assets for \$102.5 million, exclusive of transactional costs. To finance this acquisition, which included \$5.1 million of inventory, we used the proceeds from our then-existing senior term loan credit facility, as described in "-Liquidity and Capital Resources." As part of this transaction, we recorded a \$1.5 million pretax loss for the early extinguishment of debt related to the write-off of financing fees associated with a term loan refinanced in connection with the acquisition. The New Pain Products did not have separable

assets and liabilities associated with them, other than inventory; therefore we allocated the purchase price, including acquisition related expenses, to acquired identifiable tangible and intangible assets. Based on this allocation, approximately \$98 million of intangible assets have been recorded and will be amortized over 20 years.

Darvocet A500. We acquired a product, which we subsequently launched as Darvocet A500, from Athlon Pharmaceuticals in July 2003 for a cash closing payment and royalties based on the sales of this product and other defined propoxyphene and acetaminophen products we subsequently developed or acquired. Due to safety concerns about the potential for liver toxicity from large doses of acetaminophen, the FDA established a 4,000 mg maximum daily dose for adults. Containing only 500 mg of acetaminophen, compared to 650 mg in Darvocet-N 100, new Darvocet A500 taken at the daily dose, provides 1,000 mg less acetaminophen than the FDA limit. Because many patients continue taking over-the-counter pain relievers and sleep aids containing acetaminophen in addition to a prescription pain reliever, Darvocet A500 reduces the likelihood of exceeding the recommended daily limit for acetaminophen when taken up to six times per day, without sacrificing analgesic efficacy. We received FDA approval of Darvocet A500 on September 10, 2003, and launched the product nationally in early October 2003. We recorded a \$4.7 million acquisition cost as an intangible asset. We performed an impairment analysis using an updated sales forecast as of December 31, 2003 and have written off the entire value of the intangible asset.

We also entered a three-year services agreement with Athlon Pharmaceuticals to provide sales support in designated territories throughout the United States for the Darvocet A500 product. Athlon received a fixed monthly fee of \$1.2 million for the sales support services, and was entitled to potential milestone payments based on the sales of this product and other defined propoxyphene and acetaminophen products we subsequently developed or acquired. This agreement was effective October 1, 2003 and has a stated term of 36 months. We have initiated legal proceedings against Athlon and have terminated this agreement. See "--Liquidity and Capital Resources--Commitments and Contingencies" and Note 11 of Notes to Consolidated Financial Statements included elsewhere in this report.

Darvon and Darvocet Product Lines. On March 28, 2002, we acquired the U.S. rights to the Darvon and Darvocet branded product lines, which treat mild-to-moderate pain, and existing inventory from Eli Lilly. We acquired these product lines and related intangible assets for \$211.4 million, exclusive of transactional costs. To finance this acquisition, which included \$1.8 million of inventory, we used the proceeds from our then-existing senior secured credit facilities and senior subordinated notes, as described in "--Liquidity and Capital Resources." The Darvon and Darvocet product lines did not have separable assets and liabilities associated with them, other than inventory. Therefore, we allocated the purchase price, including acquisition related expenses, to acquired tangible and intangible identifiable assets.

Brethine Product Line. On December 13, 2001, we acquired the Brethine branded line of products from Novartis for \$26.6 million. We used borrowings of \$25.0 million, exclusive of transactional costs, under our then-existing senior credit facilities and cash on hand to pay the purchase price. The Brethine product line did not have separable assets and liabilities associated with it. Therefore, we have allocated the purchase price to acquired tangible and intangible identifiable assets.

M.V.I. and Aquasol Product Lines. On August 17, 2001, we acquired the M.V.I. and Aquasol branded lines of critical care injectable and oral nutritional products from AstraZeneca for \$52.5 million, exclusive of transactional costs, paid at closing, plus additional consideration described below. We funded this purchase price with increased borrowings under our then-existing senior credit facilities. Our M.V.I. and Aquasol product line acquisition agreement was amended on July 22, 2003. As amended, it provided for two \$1.0 million guaranteed payments, which were made in August 2002 and 2003, eliminated a contingent payment of \$2.0 million that was potentially due in August 2003 under the original agreement, and provided for a future contingent payment of \$43.5 million potentially due in August 2004, depending on the status of certain

reformulation activities being carried out by the seller and regulatory approval of the reformulation by the FDA. The amount of the \$43.5 million contingent payment was to be reduced by \$1 million per month if the conditions for the contingent payment had not occurred by December 31, 2002. The conditions for the contingent payment were not met by the required date, so the amount of the contingent payment had decreased by \$12.0 million by the end of December 2003. Such conditions were satisfied in January and February 2004, fixing the liability at \$31.5 million. As of December 31, 2003, this contingent obligation had not been recorded as a liability on our consolidated balance sheet and will be recorded in the first quarter of 2004. Also on July 22, 2003, the M.V.I. supply agreement with the seller was extended through 2008, subject to early termination rights by us on six months' notice given at any time, and by the supplier on twenty-four months notice given at any time on or after August 17, 2004. The M.V.I. and Aquasol product lines did not have separable assets and liabilities associated with them other than inventory, therefore we have allocated the remaining purchase price to acquired identifiable intangible assets.

Product Disposition

On April 26, 2004, we sold our M.V.I. and Aquasol product business to Mayne Pharma for \$105 million, subject to adjustments based on inventory levels at closing and other post-closing obligations. A portion of the closing payment is held in escrow to satisfy our post-closing obligations under the agreement. In addition, we are entitled to royalties on sales levels, above specified thresholds, of the M.V.I. line extension product that does not contain vitamin K, which we developed. At the closing of the transaction, we paid to AstraZeneca AB the \$31.5 million payment due in August 2004, which was discounted to approximately \$31.0 million. This payment represents a deferred purchase price payment for the original acquisition of the M.V.I. product business from AstraZeneca.

Restatement of Previously Issued Financial Statements

We are restating our financial statements for the first, second and third quarters of both 2002 and 2003 and for the year 2002. The restatements are reported in this Annual Report on Form 10-K for the year ended December 31, 2003 and will be reported in amendments to our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2003, June 30, 2003 and September 30, 2003. The restatements correct the Company's revenue recognition of certain transactions, including specific product sales in 2003, that did not satisfy all of the conditions for recognition of revenue under SFAS 48 and/or SAB 101, increase reserves for product returns and record other adjustments to our revenue reserves for 2003, and reflects a different accounting treatment for our acquired products.

On February 27, 2004, our Board of Directors appointed a committee consisting of all of the non-employee members of our Board of Directors (the "Special Committee") to conduct an inquiry into unusual sales in our Brethine and Darvocet product lines and other matters during the second half of 2003. King & Spalding LLP, an independent law firm, and Deloitte & Touche USA LLP, as independent forensic accountants, were engaged to assist the Special Committee in this inquiry.

In connection with the Special Committee's inquiry, we determined that certain matters required a material adjustment to the 2003 financial information included in our February 5, 2004 press release and the financial information for the period ended September 30, 2003 included in our quarterly report on Form 10-Q for that period. On March 30, 2004, we also announced that material adjustments may be required to the 2003 financial information included in our previous Form 10-Q reports filed in 2003 for the periods ended March 31, and June 30, 2003. We have determined that these reports on Form 10-Q will also require material adjustments.

In addition to the accounting treatment adjustments identified in connection with the Special Committee's investigation, we have identified other adjustments that affect the 2003 financial information that we had reported in our February 5, 2004 press release. These adjustments include:

- a charge of \$15.9 million due to the impairment of our Brethine intangible asset recorded in the fourth quarter of 2003;
- a \$4.7 million impairment charge in the fourth quarter of 2003 which represents the entire intangible asset recorded in the third quarter relating to the acquisition of Darvocet A500;
- a \$7.3 million increase in our returns reserve for sales of Brethine and Darvon/Darvocet products in the fourth quarter of 2003;
- a \$2.7 million increase in our inventory obsolescence reserve in the fourth quarter of 2003;
- a \$3.2 million increase in our chargeback reserve for sales in the fourth quarter of 2003 for our Oramorph product; and
- a valuation allowance of \$10.0 million as an offset against our deferred tax asset as of December 31, 2003.

In addition to the 2003 adjustments arising in connection with the Special Committee's investigation and the additional adjustments identified above, we are restating our financial statements for the year ended December 31, 2002 and for the periods ended March 31, June 30, and September 30, 2002 and 2003 to treat each of our major product line acquisitions as acquisitions of assets that do not constitute a business. On January 14, 2004 and April 26, 2004, we received letters from the SEC's Division of Corporate Finance commenting on, asking questions about, and seeking additional disclosure with respect to certain of our periodic reports. Following these discussions with the Division of Corporate Finance and based on additional analyses, we have changed the accounting treatment used from treating the acquisitions as business combinations to treating them as asset acquisitions. Accordingly, no portion of the purchase price for these acquisitions is allocated to goodwill, and the amount previously allocated to goodwill is instead allocated to the other identifiable acquired assets, including assets with definite lives. As a result, our direct costs in 2002 are greater than the amount previously reported by \$6.8 million due to the increase in amortization expense resulting from a greater amount of purchase price being allocated to assets with definite lives, and our direct costs in 2003 are greater than the amount we reported in our February 5, 2004 press release for 2003 by \$9.1 million.

We have reduced the net revenue and diluted earnings per share by \$57.7 million and \$2.35, respectively, from the results reported in our February 5, 2004 press release as a result of the identified adjustments. The financial results reported in this Form 10-K have incorporated these adjustments.

The following table summarizes the adjustments we have made to the financial information for the year ended December 31, 2003 that we had reported in our February 5, 2004 press release. We will also make significant adjustments to the financial information reported in our quarterly reports on Form 10-Q for the first three quarters of 2003. Adjustments from the Special Committee's investigation are discussed in "-- Special Committee Investigation."

	Revenue	Pre-Tax Income \$ in millions, except per share data	Net Income
Consignment Sale / Reversal of Revenue:			
Calcitriol (A)	\$ (1.6)	\$ (1.0)	\$ (0.6)
AzaSan 75mg and 100 mg (A)	(0.4)	(0.4)	(0.3)
Darvocet A500 (A)	(9.0)	(8.1)	(4.9)
Calcitriol (Puerto Rican wholesaler) (B)	(4.5)	(4.5)	(2.7)
Brethine (new wholesaler) (C)	(20.6)	(17.9)	(10.8)
Return Reserves:			
Brethine (second-tier wholesaler) (D)	(6.8)	(6.8)	(4.1)
Darvocet N 100 (E)	(4.3)	(4.3)	(2.6)

	Revenue	Pre-Tax Income \$ in millions, except per share data	Net Income
Brethine (10 and 100 count)	(3.5)	(3.5)	(2.1)
Darvon/Darvocet	(3.8)	(3.8)	(2.3)
Chargeback Reserves:			
Oramorph and other products	(3.2)	(3.2)	(1.9)
Inventory Obsolescence:			
Darvocet A500 (F)		(3.0)	(1.8)
Brethine (C)		(1.2)	(0.7)
Other products		(2.7)	(1.6)
Impairment of Intangible Assets:			
Brethine		(15.9)	(9.8)
Darvocet A500 (F)		(4.4)	(2.7)
Other intangible assets		(0.8)	(0.5)
Change in Accounting for Product Acquisitions:			
Amortization		(9.1)	(5.6)
Taxes:			
Change in tax rate			(2.0)
Deferred tax allowance			(10.0)
Total Adjustments	<u>(\$57.7)</u>	<u>(\$90.6)</u>	<u>(\$67.0)</u>
Fully Diluted EPS			<u>\$ (2.35)</u>

- (A) See numbered paragraph (1) under “- Special Committee Investigation” below. The restatement of first quarter revenues for our calcitriol and AzaSan products and the restatement of third quarter revenues for our Darvocet A500 product, each of which will be reflected in our restated report on Form 10-Q for that quarter, will be significant.
- (B) See numbered paragraph (3) under “- Special Committee Investigation” below.
- (C) See numbered paragraph (4) under “- Special Committee Investigation” below.
- (D) See numbered paragraph (5) under “- Special Committee Investigation” below.
- (E) See numbered paragraph (6) under “- Special Committee Investigation” below.
- (F) These numbers are net of amortization. See numbered paragraph (2) under “- Special Committee Investigation” below.

2003 Financial Summary

Our 2003 net revenues from pharmaceutical products were \$122.0 million, \$6.4 million less than our 2002 net revenues. Our net revenues were affected positively by the December 2003 acquisition of the New Pain Products from Elan. These products contributed \$14.5 million to our 2003 net sales. In addition, we recognized \$3.0 million from net revenues associated with products we launched in 2003. The net revenues generated by our principal product line, the Darvon/Darvocet family of products, were essentially flat year over year, although on an annualized basis product sales declined. The principal reasons for the decline in net revenues were a decline in the net revenues recorded for our Brethine line and, to a lesser extent, a decline in the net revenues of our M.V.I. product line. Our Brethine product line experienced unusually high product returns in the second half of 2003 which resulted in part from an unanticipated market dynamic when we discontinued selling Brethine injectable in its 100 count presentation. After discontinuing sales of

the 100 count containers, wholesalers began returning the 100 count containers rather than depleting their inventories. Additional reserves recorded by us in the fourth quarter of 2003 to cover additional returns of Brethine injectable 100 count further reduced our net revenues. In addition, sales of the M.V.I. product line were also significantly down from the previous year. We sold this product line to Mayne Pharma (USA) in April 2004.

Our liquidity in 2004 will be affected significantly by 2003 product sales. In 2003, we sold products to wholesalers on terms permitting the return of the product within six months if not resold by the wholesaler, including approximately \$9 million of launch quantity Darvocet A500 sold in the second half of 2003. In addition, during the second half of 2003, we sold \$20.5 million of Brethine injectable product to a specialty wholesaler and \$10.4 million of our Darvocet N-100, 500 count bottles, to repackagers that resulted in wholesaler channel inventory levels significantly exceeding our target levels. For more detail about our revenue recognition accounting policy, including the establishment of our revenue reserves, see “—Critical Accounting Policies; Revenue Recognition”. In addition to the special return rights granted to wholesalers on certain of our products, each of our products may be returned to us near the expiration date of the product. If the wholesalers exercise their rights of return for these or other products, the issuance of either a credit on future sales or a cash payment resulting from such returns could have a material effect on our liquidity in 2004. In addition, we are accounting for the shipments made to the specialty wholesaler under the consignment model. We have received payment for these shipments but will only record revenue when the wholesaler sells the product. Thus, we will record revenue in 2004 on the Brethine injectable product sold to this specialty wholesaler in 2003 for which we will not receive any additional cash payments. Finally, to the extent that wholesaler channel inventories of our products exceed appropriate levels, our sales of these products in subsequent periods may be adversely affected.

The Development Services Division experienced modest growth in net revenues over 2002 while we increased the use of this division’s capabilities to develop both line extensions and new products for our Pharmaceuticals Division. Our Development Services Division provided over 86,000 hours of service in furthering the line extension efforts on our product line, as well as assisting in the transfer of manufacturing from third parties to our own facilities. These hours are reflected as expenses under research and development.

We continue to invest both money and Development Services Division capacity to our internal research and development efforts. In 2003, our research and development expense was \$21.8 million as we furthered the development of products in our internal pipeline and expanded our intellectual properties portfolio. We received \$16.5 million of royalties in 2003 as a result of past Research and Development Division efforts. Our Research and Development program yielded one regulatory approval for three dosage strengths of one product in 2003. We launched the product in the first quarter and subsequently licensed the product to a third party in the fourth quarter. Our intellectual property portfolio increased in 2003 when we received 10 newly issued United States patents and filed an additional 10 patent applications with the U.S. Patent and Trademark Office. We also continue to pursue our patent litigation claims against several parties, see Note 11 of Notes to Consolidated Financial Statements included elsewhere in this report.

On August 5, 2003, we entered into a merger agreement with CIMA LABS INC. (“CIMA”). The completion of the merger was subject to several conditions and contained customary termination rights by each party in the event of higher unsolicited offers by a third party. During the fourth quarter of 2003, we announced the termination of our merger agreement by CIMA in light of a competing offer for CIMA by a third party. As a result, we received an \$11.5 million termination fee from CIMA, as provided in the terminated merger agreement, against which \$5.9 million of merger-related fees and expenses were applied. The net amount of \$5.6 million is recorded as other income on our consolidated statement of operations.

In 1994, we organized Endeavor Pharmaceuticals, Inc. ("Endeavor") with several investors to fund the development of hormone pharmaceutical products, initially focusing on several generic hormone products already under development by us. Based on subsequent investments by other investors, our interest, assuming conversion, had been reduced to approximately 10% of the fully diluted common equity of Endeavor. In the fourth quarter of 2003, Endeavor sold substantially all of its assets to a third party. As part of this transaction, we recorded a pretax gain of \$1.8 million for the sale of our investment in Endeavor. This gain is included in other income on our consolidated statement of operations. As of December 31, 2003, we no longer had any investment in Endeavor. For additional information on our investment in Endeavor, see Note 8 of Notes to Consolidated Financial Statements included elsewhere in this report.

Special Committee Investigation

On February 27, 2004 during the regularly scheduled meeting of the Company's full Board of Directors, the Board appointed a Special Committee of all non-employee directors to conduct an inquiry into unusual sales in our Brethine and Darvocet product lines during the second half of 2003. The Board of Directors requested the inquiry after receiving information during the meeting that certain large sales transactions involving these product lines could negatively impact 2004 sales. That same day, the Special Committee retained King & Spalding LLP, an independent law firm, to assist in its inquiry. During the week of March 1, 2004, King & Spalding, in turn, retained Deloitte & Touche USA LLP, an independent accounting firm, as forensic auditors to assist in the inquiry. Under the direction of the Special Committee, King & Spalding and Deloitte & Touche began work on the inquiry immediately.

Before the opening of trading on March 1, 2004, the first business day after the appointment of the Special Committee, the Board of Directors announced the appointment of the Special Committee and withdrew the Company's previously announced earnings guidance for the first quarter and full year of 2004. The Board of Directors also announced that, depending on the results of the inquiry, adjustments to the Company's 2003 financial results, which were previously announced in a February 5, 2004 press release and reported in Quarterly Reports on Form 10-Q for the first three fiscal quarters of 2003, might be necessary.

The Special Committee, with the assistance of counsel and accounting experts, conducted an extensive investigation that consisted of a review of over 1,000,000 pages of documents and the interview of over 35 aaiPharma employees, officers, directors and other parties. During the course of the inquiry, the Special Committee's scope expanded beyond its initial charge to include activities affecting the recognition of revenue in 2003, and other matters. In a press release issued on April 27, 2004, the Company identified financial adjustments relating to the recognition of revenue on certain transactions in 2003, and announced that it expected the reduction of revenue recognized for 2003 to be a material amount.

As described in more detail below, as a result of the inquiry we have determined that we must amend our quarterly reports on Form 10-Q for each of the first three quarters of 2003 to restate our financial statements for the first three quarters of 2003 to reflect revised accounting and revenue recognition. These adjustments to our previously reported 2003 financial information relate to the following transactions identified during the Special Committee's inquiry:

(1) In connection with our new product launches in 2003 of calcitriol, AzaSan 75 mg and 100 mg, Darvon Compound 32, and Darvocet A500, initial launch quantities of these products were sold pursuant to "guaranteed sale" conditions under which we agreed to accept returned product six months after the date of purchase, if not resold by then. Revenue was recognized for these sales upon shipment without the establishment of any special reserves to account for these return rights. Because these launches were into new markets or were products with which we did not have applicable or analogous historical experience, and because most of the sales for these products had returns provisions inconsistent with our normal returns provisions, we have concluded that we did not have the ability to reasonably estimate

returns, and that revenue for these sales should not have been recognized until all of the conditions of SFAS 48 were met.

Since all of the conditions of SFAS 48 had not been met for these sales of calcitriol, AzaSan 75mg and 100mg, and Darvocet A500 products, revenue will be recorded as if the sales were consignments. Calcitriol revenues have been reduced by \$1.6 million, AzaSan revenues have been reduced by \$0.4 million and Darvocet A500 revenues have been reduced by \$9.0 million. Under the consignment model, upon shipment of product we invoice the wholesaler, record deferred revenue at gross invoice sales price and classify the inventory held by the wholesalers as consignment inventory at our cost of such inventory. We will recognize revenue (net of discounts, rebates, sales allowances and accruals for returns) when the consignment inventory is sold by the wholesalers, as quantified using data from the wholesalers and other third-party information sources. We will continue to recognize revenue on these products on this basis until such time as we develop sufficient historical experience on which to reasonably estimate returns and all other conditions under SFAS 48 are met. With respect to Darvon Compound 32, sales of this product were not material and specific returns reserves for this product were established in 2003 in connection with our decision to voluntarily withdraw this product from the market.

(2) In July 2003, we acquired a product that we subsequently marketed as Darvocet A500. In connection with this acquisition, we entered into a purchase agreement to acquire the rights to this product for a cash closing payment and an obligation to make royalty payments based on sales of this product and any subsequently developed or acquired defined propoxyphene and acetaminophen products. At that time, we also entered into a service agreement with the seller providing for a contract sales force to co-promote this product. We made an upfront cash payment when this service agreement was executed and were obligated to make additional monthly payments for 36 months once the product was commercially launched (which occurred in October 2003) and potential milestone incentive payments based on the sales of this product and any subsequently developed or acquired defined propoxyphene and acetaminophen products. On June 4, 2004 we sent a notice of termination of the Athlon Service Agreement to Athlon and we have initiated litigation against Athlon with respect thereto. See "Item 3. Legal Proceedings – Contract Sales Force Litigation."

In the 2003 financial statements included in our Form 10-Q for the period ended September 30, 2003, we recorded an intangible asset in the amount of the closing payment with a definite life of 18.5 years. We have re-evaluated our allocation of values associated with the concurrent agreements discussed above and, with the assistance of third-party valuation consultants, have determined the fair value of the intangible asset acquired as of the date of the acquisition to be greater than the closing date payment. Accordingly, we have re-allocated a portion of the value associated with the service agreement to the purchase price of the intangible asset. Our adjusted financial statements for the third quarter of 2003 reflect an intangible asset of \$4.7 million.

Our business plan for our Darvocet line extensions, including Darvocet A500, was based in part on the belief that these products would not be subject to immediate competition from generic products, although they would be subject to potential generic competition. We have learned, however, that in some jurisdictions pharmacists may fill prescriptions written for Darvocet A500 with generic products that, though not recognized by the FDA as therapeutically equivalent to Darvocet A500, may be deemed by the pharmacist to be therapeutically equivalent. It is our understanding that a pharmacist's profit margin on these generic products generally exceeds the pharmacist's profit margin on Darvocet A500. As described above, we have also initiated litigation with respect to the performance of the contract sales force in co-promoting this product. These factors may have accounted for lower revenues from Darvocet A500 than we had initially estimated.

In March and April of 2004, we began to receive significant return requests for Darvocet A500 product sold under the "guaranteed sale" conditions noted above. We subsequently contacted our wholesaler customers

and utilized actual inventory levels, in conjunction with third-party prescription data, to re-evaluate our forecasted sales of the product. This identified a potential impairment of the acquired Darvocet A500 intangible asset recorded in the third quarter 2003. We conducted a review for impairment in accordance with SFAS 142 and SFAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," and have recorded an impairment loss for the full amount of this intangible asset, \$4.7 million, in the fourth quarter 2003. In addition, we have re-evaluated and reserved \$3.0 million for potential inventory obsolescence for quantities of the Darvocet A500 product on hand and in the distribution channel in excess of estimated demand.

(3) We recorded approximately \$4.65 million in revenue in the third quarter of 2003 for the sale of calcitriol product to a Puerto Rican wholesaler that we have concluded should be reversed in the period in which it was originally recorded. Our adjusted financial statements for the third quarter of 2003 have reserved for substantially the full amount of the resulting inventory, as a substantial amount has been returned and we do not expect the remainder of this inventory to be sold.

(4) There were substantial sales transactions at the end of the third and fourth quarters of 2003 with a new wholesaler of our Brethine product resulting in wholesaler channel inventory levels significantly exceeding our target levels. We also continued to sell Brethine product during the fourth quarter of 2003 to our established wholesaler customers, further adding to channel inventory levels. The specialty wholesaler was expected to open new distribution channels, for which we have concluded we did not have the ability to reasonably estimate returns, and all conditions of SFAS 48 were not met. In addition, sales of other products to this new wholesaler during the third quarter of 2003 appear to have been on special terms that do not satisfy the conditions of SFAS 48. We had recorded revenue for these sales upon shipment of the products.

The net revenues for these sales to the new specialty wholesaler of \$12.3 million of Brethine and \$3.9 million of other products in the third quarter of 2003 and \$8.3 million of Brethine in the fourth quarter of 2003 have been reversed in the respective periods they were originally recorded. Revenue will be recognized as sales meet the criteria of SFAS 48. In addition, the significant increase in inventory levels in the channel due to transactions with this new wholesaler caused us to re-evaluate our overall reserves for our Brethine products. As a result of our analyses, we have increased our inventory obsolescence reserves by \$1.2 million for specific inventory not expected to sell through before product expiration.

(5) There were significant returns in the first quarter of 2004 from a second-tier wholesaler of our Brethine products that were inconsistent with our historical returns experience. The bulk of these products was initially sold by us during the first half of 2003 and was acquired by the second-tier wholesaler in purchases from us and from one of our principal wholesalers. Based on our knowledge regarding the market factors affecting these requested returns, we now believe that this inventory was purchased by the wholesaler for a particular opportunity that did not materialize.

A specific returns reserve of \$6.8 million, which included \$3.3 million in the first quarter, \$2.6 million in the second quarter and \$0.9 million in the third quarter, has been recorded for these sales and for the related inventory in our restated 2003 financial statements.

(6) There were sales transactions in the fourth quarter of 2003 of our Darvocet-N 100 500-count bottle product to repackagers resulting in channel inventory levels significantly exceeding our target levels.

Due to the level of inventory that existed in the market, we performed additional procedures to determine whether there might be higher than anticipated returns due to future expiration of product. This review included direct communication with the repackager that had purchased the greatest volume of this product during the fourth quarter to understand estimated usage compared to inventory levels. Based on this review,

we have concluded these sales met the conditions of SFAS 48 for recognition, but we have increased our returns reserve by \$4.3 million to adequately cover potential product expiry concerns.

In April 2004, in connection with their audit of the Company's consolidated financial statements for the year ended December 31, 2003, the Company's independent auditors identified and communicated to the Company and the Audit Committee two "material weaknesses" (as defined under standards established by the American Institute of Certified Public Accountants) relating to our accounting and public financial reporting of significant matters and to its initial recording and management review and oversight of certain accounting matters. In addition, at that time, the independent auditors identified and communicated to the Company and the Audit Committee a "reportable condition" (as defined under standards established by the American Institute of Certified Public Accountants) relating to our internal controls over our financial reporting for investments.

As a result of the information developed during the Special Committee's review, we identified a number of deficiencies in our systems of internal accounting controls. The internal control deficiencies related to, among other things, a lack of adequate policies on revenue recognition, and a lack of sufficient control processes and procedures to effectively monitor and manage wholesaler inventory levels, to ensure adequate contract approval oversight, and to ensure effective communication among sales, marketing, finance and legal staff regarding the terms and conditions of new product launches. We have also concluded that we did not have an adequate demand-based budgeting approach, and with respect to the sales of pharmaceutical products, our finance and accounting personnel lacked adequate training on the application of revenue recognition principles and the establishment of product return reserves.

We determined that we need to dedicate additional attention and resources to develop formal revenue recognition protocols and training programs, to implement appropriate contract approval policies and financial reporting structures and processes, and to ensure that the company has qualified employees overseeing compliance with applicable accounting principles, securities laws and regulations. Our new management has undertaken a substantial process to improve our existing policies, processes and personnel. In March of 2004, Dr. Sancilio, the Company's Executive Chairman and Chief Scientific Officer, replaced Dr. Tabbiner as Chief Executive Officer, and Gregory F. Rayburn was appointed Interim Chief Operating Officer. In April 2004, Timothy R. Wright was appointed President of the Company's Pharmaceuticals Products Division. Gina Gutzeit was appointed as Interim Chief Financial Officer in May 2004.

Significant Development Agreement

We have a development agreement with a customer that provides for us to receive contingent periodic royalties based on sales of the customer's product and obligates the customer to use us on a fee-for-service basis for a product life cycle management project related to the product. The customer is a major pharmaceutical company with net assets in excess of \$2.0 billion. The development agreement relates to a product with respect to which we have licensed intellectual property that we developed in the past. We have recognized product development revenues under this agreement for the periodic payments based on our customer's sales of the product, and have recognized development services revenue related to the product life cycle management project. Product development revenues from this agreement were \$13.0 million in 2003, \$16.9 million in 2002 and \$14.9 million in 2001. We recognized no research and development expense in 2003, 2002 and 2001 associated with the payments we received in those years. The expense of our work associated with these revenues was recognized primarily in 1997 through 1999. We do not anticipate incurring significant expense associated with the product development revenues under this agreement in future periods. Development services revenues associated with this agreement were \$2.7 million in 2003, \$4.7 million in 2002 and \$6.3 million in 2001. Because of the research and development nature of our activities in this product life cycle management project and the potential that these activities could result in continuation of product development revenues into the future, we have recorded our costs incurred in this project as research

and development expense--\$1.0 million in 2003, \$0.7 million in 2002 and \$2.3 million in 2001. Accordingly, for our development services business unit, we have recognized no expense associated with the development services revenue arising under this agreement, as this expense was recognized by our product development business unit.

We are entitled to receive these royalties based on sales of the customer's product only if we make available exclusively to our customer our product development and reformulation services with respect to a limited group of drugs that include the customer's product. This obligation does not prevent us from engaging in these development and reformulation activities for products that we may develop for ourselves. As we remain available to provide the customer with these services on this basis in a calendar quarter, we will be entitled to royalties based on the level of sales over a prior monthly period of the product. The customer is obligated to make these quarterly payments based on whether defined market events have occurred in the prior measurement month--e.g., if the defined market events have not occurred during three consecutive months, we would be entitled to royalties in three consecutive quarters, with, for example, the amount of the royalties in the first quarter being based on product sales in the first month. However, if we do not continue to provide these development and reformulation services on the exclusive basis described above in any quarter, we will not be entitled to the royalties for that quarter and all subsequent quarters. Under the agreement, we have the right, at any time, to terminate our obligation to provide the development and reformulation services on an exclusive basis. Accordingly, we do not recognize product development revenues under this agreement in any quarter until we have satisfied the exclusivity requirement for that quarter.

The development agreement also requires the customer to use a minimum amount of our development services at standard rates on the product life cycle management project in specified calendar quarters. In 2001, 2002 and 2003 the project was at the minimum contractual levels. The customer is obligated to continue the project at the minimum level in 2004, which is approximately \$0.7 million.

In April 2004, we entered into an agreement to receive a prepayment of amounts that would otherwise be paid to us quarterly through the second quarter of 2005. These payments would have aggregated \$15.4 million. Our agreement to receive a prepayment of these amounts applied a 5% per annum discount from the date the payment would otherwise be due to the date paid. In April 2004, we received approximately \$15.0 million in gross proceeds from prepayments made pursuant to this agreement. We do not anticipate that we will receive further material payments in connection with this significant development agreement in the future. Our obligations under the significant development agreement with respect to the prepaid amounts continue through the second quarter of 2005, and we will recognize revenue associated with the prepayment as we satisfy these contractual obligations during this period.

Results of Operations

The following table presents the net revenues for each of our business units and our consolidated expenses and net income (loss) and each item expressed as a percentage of consolidated net revenues:

	Years Ended December 31,					
	2003		2002 (as restated)		2001	
Net revenues:						
Product sales	\$ 122,021	54%	\$ 128,462	56%	\$ 27,448	19%
Product development	16,468	7	19,610	9	20,426	14
Development services	86,488	39	82,438	35	93,199	67
	<u>\$ 224,977</u>	<u>100%</u>	<u>\$ 230,510</u>	<u>100%</u>	<u>\$ 141,073</u>	<u>100%</u>

Direct costs (excluding depreciation and royalty expense)	\$ 114,837	51%	\$ 90,697	39%	\$ 67,197	48%
Selling	39,534	18	23,077	10	13,749	10
General and administrative	40,463	18	40,109	17	26,538	19
Research and development	21,788	10	20,853	9	10,482	7
Depreciation	7,973	4	7,156	3	7,755	5
Royalty expense	1,095	-	-	-	-	-
Intangible asset impairment	20,600	9	-	-	-	-
Direct pharmaceutical start-up costs	-	-	-	-	2,123	2
Income (loss) from operations	(21,313)	(9)	48,618	21	13,229	9
Interest expense, net	21,078	9	19,366	8	3,646	3
Loss from extinguishment of debt	(1,511)	(1)	(8,053)	(3)	-	-
Other income (expense), net	6,697	3	461	-	(444)	-
Provision for (benefit from) income taxes	(4,502)	(2)	8,542	4	3,199	2
Net income (loss)	(32,703)	(15)	13,118	6	5,940	4

Year Ended December 31, 2003 Compared to Year Ended December 31, 2002

Our consolidated net revenues for the year ended December 31, 2003 decreased 2% to \$225.0 million, from \$230.5 million in 2002. The decrease is attributable to lower net revenues recorded from the sale of our pharmaceutical products and, to a lesser extent, a reduction in product development revenues associated with our significant development contract.

Net revenues from product sales decreased to \$122.0 million in 2003, from \$128.5 million in 2002. The decrease in net revenues is attributable to reduced net sales of our Brethine line and, to a lesser extent, reduced net sales of our M.V.I. line:

These reduced sales were mitigated in 2003 by the introduction of several new products, including the New Pain Products acquired from Elan in December 2003, our Darvocet A500 line extension introduced in September 2003 and our calcitriol injection product introduced in March 2003. These new product offerings contributed an aggregate of \$17.4 million to 2003 net revenue, of which \$14.5 million was attributable to sales of the New Pain Products. In addition, price increases, primarily related to our Brethine injectable product and Darvon and Darvocet product lines, accounted for \$9.5 million of our 2003 net revenue. Net revenues from commercial manufacturing of products marketed by other pharmaceutical companies, which are included in product sales, contributed \$2.8 million and \$4.1 million to net revenues from product sales in 2003 and 2002, respectively.

Net revenues from product development decreased 16% in 2003 to \$16.5 million, or 7% of net revenues, from \$19.6 million, or 9% of net revenues, in 2002, primarily due to lower revenues related to our significant development agreement in 2003 and to third-party licensing payments which we had previously deferred and were amortized into revenue in 2002 and prior years. No previously deferred revenues were recognized in 2003.

Net revenues from our development services business increased 5% in 2003 to \$86.5 million, from \$82.4 million in 2002. This increase was principally attributable to higher demand for our European bioanalytical and clinical services and our U.S. analytical capabilities, partially offset by lower fee-for-service revenues from lower demand for our clinical manufacturing and formulations services and under our significant development agreement.

Direct costs (excluding depreciation and royalty expense) increased \$24.1 million, or 27%, to \$114.8 million in 2003, from \$90.7 million in 2002. This increase in direct cost dollars resulted from higher product costs of \$8.8 million, increased inventory reserves of \$11.2 million related to estimated reserves for excess wholesaler inventories in excess of anticipated demand in 2003 and increased amortization expense of \$3.0 million related to product rights for acquired products. Direct costs as a percentage of net revenues increased to 51% in 2003 from 39% in 2002.

Selling expenses increased 71% in 2003 to \$39.5 million, or 18% of net revenues, from \$23.1 million, or 10% of net revenues, in 2002. This increase is primarily due to expenses incurred by our product sales business associated with developing our product sales force and marketing and promoting our new products. As of December 31, 2003, our pharmaceutical sales force was approximately 200, including 105 outside sales professionals added in October 2003 under an agreement with Athlon Pharmaceuticals, from whom we acquired our Darvocet A500 product, as compared to 50 sales professionals at December 31, 2002. In 2004, we have reviewed the performance of the Athlon sales force performance and have terminated the contract.

General and administrative costs increased 1% in 2003 to \$40.5 million, or 18% of net revenues, from \$40.1 million, or 17% of net revenues, in 2002. This increase was primarily due to additions to our corporate infrastructure to accommodate the expansion of our overall business, expenses related to the management build-up for our product sales business and increased product related insurance costs, partially offset by lower legal fees and employee benefit related expenses. During 2003, we incurred legal fees and expenses in our ongoing omeprazole patent litigation against Schwarz Pharma Inc., Schwarz Pharma AG, Kremers Urban Development Co., and certain affiliates. We anticipate that we will continue to incur legal fees and expenses in connection with this litigation in 2004, as well as other litigation and investigations. See "Item 3. Legal Proceedings" for additional information regarding this litigation and other pending litigation that may significantly increase our legal expenses in 2004.

Research and development expenses increased 4% in 2003 to \$21.8 million from \$20.9 million in 2002. These amounts represented 10% of net revenues in 2003 and 9% of net revenues in 2002. We incurred significant project spending in 2003 related to our ProSorb-D pain management product and development work on line extensions for our pain management and critical care products. We target annual research and development expenses to be approximately 8% to 10% of our estimated net revenues.

Royalty expenses in 2003 were \$1.1 million. We accrue royalties based on revenues generated by certain acquired products, including our Darvocet A500 product and our calcitriol product. These royalty expenses will continue in 2004. No similar royalty expenses were incurred in 2002.

In December 2003, we recorded a \$15.9 million charge due to the impairment of an intangible asset associated with our acquired Brethine product. The then-anticipated introduction of generic competition for this product (which subsequently occurred in May 2004) affected our future anticipated revenues, which negatively impacted the carrying value of the acquired intangible assets. We also recorded a \$4.7 million write down of the full amount of the intangibles assets related to the Darvocet A500 product we acquired in 2003. In March and April of 2004, we experienced significant requests for returns of Darvocet A500. We re-evaluated our sales forecast for Darvocet A500 and identified a potential impairment of the asset. As a result of the impairment analysis, we determined that the asset needed to be written-off.

The consolidated loss from operations was \$21.3 million in 2003, compared to consolidated income from operations of \$48.6 million in 2002. This decrease was primarily due to the lower product sales and product development revenues in 2003, increased product-related costs and the intangible asset impairment charges.

Income from operations for our product sales business in 2003 was \$2.5 million, compared to \$66.9 million in 2002. This decrease resulted from the combination of reduced net sales, increases in our reserves for product returns, increased sales costs associated with the launch of Darvocet A500, and the intangible asset impairment recorded in the fourth quarter.

Income from operations for our product development business was \$16.5 million in 2003, compared to income from operations of \$19.6 million in 2002. This change resulted from the decreased revenues from our significant development agreement.

Income from operations for our development services business was \$1.0 million in 2003, compared to \$0.6 million in 2002. This increase is primarily due to increased margins in our bioanalytical and analytical businesses in 2003. The increase in revenues was the primary reason for the higher operating margins achieved in 2003.

Unallocated corporate expenses increased in 2003 to \$19.0 million, or 8% of net revenues, from \$17.1 million, or 7% of net revenues, in 2002. This higher level was due to additions to our corporate infrastructure to accommodate the expansion of our overall business.

Net interest expense increased to \$21.1 million in 2003, from \$19.4 million in 2002. This \$1.7 million increase is primarily attributable to the borrowings that funded our product line acquisitions in December 2003 and March 2002, partially offset by debt repayments and lower interest rates on our variable rate debt.

Losses from the extinguishment of debt of \$1.5 million and \$8.1 million were recorded in 2003 and 2002, respectively. These losses resulted from the write-off of deferred financing and other costs due to the refinancing of our term loan facility in December 2003 in connection with our New Pain Products acquisition and the refinancing of our prior debt facilities in March 2002 related to our Darvon and Darvocet acquisition.

Other income in 2003 includes \$5.6 million related to the termination fee, net of expenses, received from CIMA, and the \$1.8 million gain from the sale of our investment in Endeavor.

We recorded a tax benefit of \$4.5 million in 2003, based on an effective tax rate of 39%, offset by a valuation allowance of \$10.0 million because it is more likely than not that some portion of the deferred tax asset will not be realized. Our effective tax for 2002 was 39%.

Year Ended December 31, 2002 Compared to Year Ended December 31, 2001

Our consolidated net revenues for the year ended December 31, 2002 increased 63% to \$230.5 million, from \$141.1 million in the same period of 2001. Net revenues from product sales increased to \$128.5 million in 2002, from \$27.4 million in 2001, due to sales of our M.V.I., Aquasol, and Brethine products, which we acquired in the second half of 2001, and sales of Darvon and Darvocet, which we acquired at the end of the first quarter of 2002. Net revenues from commercial manufacturing of products marketed by other pharmaceutical companies, which are included in product sales, contributed \$4.1 million and \$9.9 million to net revenues from product sales in 2002 and 2001, respectively.

Net revenues from product development decreased 4% in 2002 to \$19.6 million, from \$20.4 million in 2001, primarily due to a decrease in third-party licensing revenues, partially offset by an increase in product development revenues under our significant development agreement, which increased from \$14.9 million in 2001 to \$16.9 million in 2002.

Net revenues from our development services business decreased 12% in 2002 to \$82.4 million, from \$93.2 million in 2001. This decrease was principally attributable to the redeployment of a portion of our internal resources from external revenue-producing projects to research and development projects relating to

our own pharmaceutical products, both current and future. This redeployment of resources was a strategic decision we made to expand our proprietary product development pipeline through the increased use of our development services (fee-for-service) segment's core competencies. This strategy has allowed us to better control project flow at lower costs.

Direct costs (excluding depreciation expense) increased \$23.5 million, or 35%, to \$90.7 million in 2002, from \$67.2 million in 2001. This increase in direct cost dollars resulted from the increase in revenue in 2002 and amortization expense of \$9.2 million related to product rights for acquired products. Direct costs as a percentage of net revenues decreased to 39% in 2002 from 48% in 2001. This favorable change was primarily the result of the change in the mix of revenues in 2002, with product revenues increasing to 56% of total revenues from 20% in 2001.

Selling expenses increased 68% in 2002 to \$23.1 million, from \$13.7 million in 2001. This increase was principally due to additional selling expenses incurred by our product sales business associated with marketing and promoting our entire product line, maintaining and enhancing our relationships with distributors, and growing and developing our product sales force. As a percentage of net revenues, selling expenses in 2002 increased slightly from 2001. At the end of 2002, we had 50 pharmaceutical product sales representatives, as compared to 20 at the end of 2001.

General and administrative costs increased 51% in 2002 to \$40.1 million, from \$26.5 million in 2001. This increase was primarily due to expenses related to the management build-up for our product sales business. As a percentage of net revenues, general and administrative expenses in 2002 decreased to 17%, from 19% in 2001.

Research and development expenses were approximately 9% of net revenues, or \$20.9 million, in 2002, an increase from 7% of net revenues, or \$10.5 million, in 2001. This increase resulted primarily from clinical trials started in 2002 for our ProSorb-D pain management product and line extension development of our critical care products.

There were no direct pharmaceutical start-up costs recorded in 2002, as compared to \$2.1 million in 2001. These costs were incurred prior to our acquisition of any pharmaceutical product lines in 2001 and were expensed as incurred.

Consolidated income from operations was \$48.6 million in 2002, or \$35.4 million higher than the prior year, and was due to the expansion of our product sales business.

Income from operations for our product sales business was \$66.9 million in 2002, compared to \$7.7 million in the prior year. This increase was attributable to the revenues and gross margin generated from our product line acquisitions, partially offset by the product rights amortization expense of \$9.2 million.

Income from operations for our product development business was \$19.6 million in 2002, compared to \$20.4 million in 2001. This change resulted from the decreased revenues under our significant development agreement, as discussed above. Our expenses associated with the development work performed under this agreement were recognized as incurred, primarily in 1997 through 1999. No significant expense was associated with the product development revenues recognized in 2002, 2001 or 2000.

We recorded income from operations for our development services business of \$0.6 million in 2002, compared to income from operations of \$8.9 million in 2001. This decrease was primarily due to the decline in development services revenue, as described above.

Unallocated corporate expenses increased in 2002 to \$17.1 million, from \$13.0 million in 2001. This increase was due to additions to our corporate infrastructure to accommodate our expansion and increased legal fees to support our intellectual property. As a percentage of net revenues, unallocated corporate expenses in 2002 decreased to 7%, from 9% in 2001.

Net interest expense increased to \$19.4 million in 2002, from \$3.6 million in 2001. This increase was primarily attributable to the net borrowings that funded our product line acquisitions.

A loss from the extinguishment of debt of \$8.1 million was recorded in 2002. This loss was due to the write-off of deferred financing and other costs related to our prior debt facilities that were refinanced in March 2002.

We recorded a tax provision of \$8.5 million in 2002, based on an effective tax rate of 39%. This rate was approximately equal to the statutory rate. Our effective tax rate for 2001 was 35%, which reflected the utilization of tax loss-carry forwards generated by our European operations.

Liquidity and Capital Resources

Historically, we have funded our business with cash flows provided by operations and proceeds from borrowings. Net cash flow provided by operating activities in 2003 was \$38.4 million, up from \$31.0 million in 2002. This increase was primarily due to the significant increase in deferred revenues on products accounted for under a consignment model, partially offset by negative cashflow changes in deferred tax assets arising from temporary differences between the tax and accounting treatment of the deferred revenues.

Net cash used in investing activities was \$114.3 million in 2003. This included \$102.5 million primarily related to our acquisition of the New Pain Products. Capital expenditures were \$11.9 million during 2003. Capital assets purchased during 2003 were primarily related to setting up and transferring the production for acquired products, purchases of information technology hardware and software and upgrading and replacing laboratory equipment.

Net cash provided by financing activities during 2003 was \$78.0 million, primarily representing net proceeds of \$160.0 million in additional borrowings under the term loan facility we entered into in December 2003, as described below, \$8.8 million of cash proceeds from the exercise of stock options and \$1.7 million related to the unamortized proceeds from the sales of our interest rate swap, partially offset by the repayment of \$93.5 million of borrowings under the then-existing revolving credit facility and the prior term loan credit facility. These repayments included \$50.0 million from the proceeds of the term loan we entered into in December 2003. The additional repayments were funded by cash from operations as part of our program to aggressively pay down our then-existing credit facility. These prepayments of our term loan indebtedness reduced our liquidity.

Net cash flow provided by operating activities in 2002 was \$31.0 million, an increase of \$10.6 million from 2001. This change was primarily related to increases in net income and accrued interest payable on our senior subordinated notes, partially offset by increases in accounts receivable and inventories related to the product lines we acquired, and prepaid financing fees related to the financing of our Darvon and Darvocet acquisition. Net cash used in investing activities was \$235.1 million in 2002, which included \$211.4 million related to our Darvon and Darvocet acquisition, \$14.1 million for the purchase of assets formerly covered by our tax retention operating lease, including our corporate headquarters in Wilmington, N.C. and a laboratory and clinical facility in Chapel Hill, N.C., and capital expenditures of \$8.5 million. Net cash provided by financing activities during 2002 was \$204.2 million, primarily representing net proceeds of \$244.5 million in additional borrowings under our debt facilities, \$10.5 million related to the unamortized proceeds from the sales of our

interest rate swap and \$3.2 million of cash proceeds from the exercise of stock options, partially offset by the repayment of \$51.9 million of borrowings in the last nine months of 2002.

In 2001, \$20.4 million of cash flow was provided by operating activities, an increase of \$5.6 million over 2000. This was primarily due to our improved management of working capital, which was strongly influenced by the timing of transactions, including our receipt of \$14.9 million of product development payments associated with our significant development agreement described above and the collection of a significant receivable associated with this agreement. Our working capital improvement was partially offset by additional working capital needed for the M.V.I., Aquasol, and Brethine product lines. During 2001, cash used in investing activities was \$81.8 million, which was primarily related to our acquisition of these branded product lines. Capital expenditures were \$6.3 million during 2001, and in March 2001, we completed a sale/leaseback transaction on manufacturing equipment, which provided cash of \$3.1 million. Cash provided by financing activities during 2001 was \$66.6 million, primarily representing net proceeds of \$78.9 million in borrowings to fund our M.V.I. and Brethine product line acquisitions and \$5.1 million of cash proceeds from the exercise of stock options, offset by repayments under our then-existing revolving credit facility of \$16.3 million.

Senior Credit Facilities

On March 28, 2002, we acquired the U.S. rights to the Darvon and Darvocet branded product lines and existing inventory from Eli Lilly and Company for \$211.4 million in cash. In connection with the acquisition, we entered into \$175 million of senior credit facilities, issued \$175 million of senior subordinated notes due 2010, repaid all \$78 million of borrowings outstanding under our prior senior credit facilities, and terminated our tax retention operating lease and purchased the underlying properties.

Our \$175 million senior secured credit facilities consisted of a \$75 million five-year revolving credit facility and a \$100 million five-year term loan facility. The term loan facility amortized over the full five-year term. The senior facilities were subsequently reduced due to repayments made under the term loan facility. In December 2003, we repaid the remaining term loan facility of \$40 million and entered into a new \$160 million term loan facility. As part of this transaction, we recorded a \$1.5 million pretax loss for the early extinguishment of debt related to the write-off of financing fees associated with the original term loan. These term loan and revolving credit facilities provided for variable interest rates based on LIBOR or an alternate base rate, at our option. On December 31, 2003, 30-day LIBOR was 1.12%.

As a result of our failure to timely file our annual report on Form 10-K for the year ended December 31, 2003, among other matters, we were in default under the December 2003 term loan and revolving credit facilities. On April 23, 2004, we refinanced these facilities with a portion of the proceeds from the M.V.I. and Aquasol Sale and with \$140 million of senior credit facilities with a syndicate of lenders, Silver Point Finance LLC ("Silver Point") as collateral agent, and Bank of America, N.A., as administrative agent. Our new senior credit facilities consist of a two-year, \$125 million senior secured term loan facility (which was fully drawn at closing) and a two-year, \$15 million senior secured revolving credit facility, of which the full amount was available for borrowing on June 9, 2004. The outstanding loans under our new senior credit facilities are payable in full on the two-year anniversary date of the closing of the facilities. Our new senior credit facilities are secured by a security interest on substantially all domestic assets, all of the stock of domestic subsidiaries and 65% of the stock of material foreign subsidiaries. Subject to exceptions set forth in the definitive documentation, loans under our new senior credit facilities are also required to be prepaid with a negotiated percentage of:

- excess cash flow, as defined;
- non-ordinary course assets sales;
- net proceeds from the sale of subordinated indebtedness;
- net proceeds from the issuance of equity issuances; and
- extraordinary receipts, as defined.

Optional reductions in revolving credit commitments and optional prepayments of term loans are subject to a prepayment fee equal to 3% for the first 9 months of the term of the facilities, 1.5% for the subsequent 9 months of such term, and 0.75% for the next 3 months of such term (with no prepayment penalty payable for the last 3 months of the term). Outstanding loans under the facilities bear interest at a rate per annum equal to a defined LIBOR rate (with a floor of 2%), plus 6.25%, or a defined reference rate (with a floor of 4%), plus 5.25%, in each case payable monthly in arrears. An additional 1% per annum unused line fee is payable on unused revolving credit commitments, payable quarterly in arrears.

The proceeds of the loans were used, together with the net cash proceeds from the M.V.I. and Aquasol Sale, to (i) fund payment of termination obligations with respect to the our interest rate hedging agreement (discussed below), (ii) refinance our then-existing senior credit facilities, (iii) fund the April 2004 interest payment due on our 11% senior subordinated notes due 2010, (iv) provide for ongoing working capital and general corporate needs, and (v) pay for fees, costs and expenses in connection with the new senior credit facilities and other corporate transactions.

Our new senior credit facilities include customary representations and warranties and customary affirmative and negative covenants, including limitations on liens, indebtedness, fundamental transactions, dispositions of assets, changes in the nature of our business, investments, acquisitions, capital and operating leases, capital expenditures, dividends, redemptions or other acquisitions of capital stock, redemptions or prepayments of other debt, transactions with affiliates, issuances of capital stock, modifications of indebtedness, organizational documents and other agreements, and retention of excess cash. The facilities also provided for financial covenants, including a minimum fixed charge ratio, a maximum senior debt to trailing twelve-month EBITDA ratio, and a covenant requiring a certain level of cash or revolver availability. Our new senior credit facilities include a covenant requiring us to file with the Securities and Exchange Commission by September 30, 2004 our annual report on Form 10-K for the year ended December 31, 2003 and other periodic reports then required to be filed under the Securities Exchange Act of 1934. Events of default under the facilities include, among others, nonpayment of principal, interest or fees, violations of covenants, inaccuracy of representations and warranties, a cross-default to our 11% senior subordinated notes due 2010 and other material indebtedness, bankruptcy events, and a change in control.

Subordinated Notes Due 2010

In March 2002, we issued \$175 million of senior subordinated unsecured notes due 2010. The proceeds from the issuance of these notes were \$173.9 million, which was net of the original issue discount. This discount will be charged to interest expense over the term of the notes. These notes have a fixed interest rate of 11% per annum and are guaranteed on a subordinated basis by all of our existing domestic subsidiaries and all of our future domestic subsidiaries of which we own 80% or more of the equity interests. Prior to March 28, 2005, up to 35% of the notes are redeemable with the proceeds of qualified sales of equity at 111% of par value. The terms of our senior credit facilities require us to repay all of the indebtedness under these facilities before we could repurchase any of the notes. On or after March 28, 2006, all or any portion of the notes are redeemable at declining premiums to par value, beginning at 105.5%. Under the terms of the indenture for the notes, we are required to comply with various covenants including, but not limited to, a covenant relating to incurrence of additional indebtedness. We were not in compliance with certain of these covenants at December 31, 2003, however defaults under these covenants have been subsequently waived.

On March 31, 2004, the lenders under our then-existing credit agreement, which was then in default as described above, exercised their right to block us from making the interest payment to holders of our senior subordinated notes due on April 1, 2004. Accordingly, we did not make that interest payment on April 1, 2004. In addition, our failure to timely file our annual report on Form 10-K for the year ended December 31, 2003 constituted a default under the indenture governing the senior subordinated notes.

On April 20, 2004, we completed a solicitation seeking the consent from holders of our senior subordinated notes to approve a refinancing or replacement of our then existing the credit facilities with our new senior credit facilities and certain amendments to, and waivers under, the indenture governing the senior subordinated notes to, among other things:

- grant a lien to secure our obligations under the senior subordinated notes, which lien is junior to the liens securing our new senior credit facilities but covers the same collateral;
- increase the interest rate of the senior subordinated from 11% per annum to 11.5% per annum effective April 1, 2004;
- suspend our obligation under the indenture to file periodic reports with the SEC until the earlier of the date that our annual report on Form 10-K for the year ended December 31, 2003 is filed with the SEC or September 30, 2004, and suspend our obligation under the indenture to furnish annual written statements of our accountants until the fifth day after the earlier of the date that our annual report on Form 10-K for the year ended December 31, 2003 is filed with the SEC and September 30, 2004;
- further limit our ability to grant liens to secure certain obligations unless the liens are subordinate to the liens securing the senior subordinated notes or are otherwise permitted under the indenture; and
- limit our ability to incur up to \$10 million of indebtedness, and to grant liens to secure that amount of indebtedness, not otherwise specifically permitted by the indenture, until our annual report on Form 10-K for the year ended December 31, 2003 is filed with the SEC or unless the indebtedness is incurred to fund an interest payment with respect to the senior subordinated debt.

Following the completion of this consent solicitation, we entered into a supplemental indenture to affect these amendments and waivers and made the interest payments that had been due on April 1, 2004, together with default interest.

We made interest payments on the senior subordinated notes of \$9.6 million in October 2003 and \$9.7 million in April 2004. The April 2004 interest payment was offset by approximately \$1.7 million received under our interest rate hedging agreement, described below.

Interest Rate Hedging Agreement

Concurrently with the issuance of our senior subordinated notes, we entered into an interest rate hedging agreement to effectively convert interest expense on a portion of the senior subordinated notes for the term of the notes from an 11% fixed annual rate to a floating annual rate equal to 6-month LIBOR plus a base rate. On February 27, 2003, and again on June 23, 2003, we sold the then outstanding hedging agreement for \$2.3 million and \$3.7 million, respectively, and replaced it with a similar interest rate hedging agreement. The amounts we received, less the interest benefits earned through the dates of sale, have been recorded as premiums to the carrying amount of the notes and are being amortized into interest income over their remaining life. This amortization will be approximately \$2.0 million annually. At December 31, 2003, we had an interest rate hedging agreement in place covering \$150 million of the notes, at a rate of 6-month LIBOR plus 7.41%. On December 31, 2003, 6-month LIBOR was 1.22%, giving us an estimated all-in rate of 8.63%. The terms of the interest rate hedging agreements, other than the base rate, were identical and were perfectly matched with the terms of the related hedged instrument.

Our obligations under the interest rate hedging agreement were secured by collateral under our then-existing senior credit facilities.

As a condition to establishing our new senior credit facilities, we terminated the interest rate hedging agreement in April 2004. Our termination obligations under the interest rate hedging agreement were approximately \$9.4 million, which amount was paid upon termination of that agreement.

Income Tax Refunds

Income tax refunds will be a source of near-term liquidity. We anticipate receiving \$4.5 million due on our 2003 tax filing and \$0.5 million for the amended 2002 tax filing.

Commitments and Contingencies

As discussed above, the conditions for the M.V.I. and Aquasol contingent payment were not satisfied by the required date, so that the potential \$43.5 million contingent payment had decreased by \$12.0 million by December 31, 2003. Such conditions were met in January and February 2004, fixing the liability at \$31.5 million. As of December 31, 2003, this contingent obligation had not been recorded as a liability on our consolidated balance sheet and was recorded in the first quarter of 2004. We discharged this obligation in April 2004.

In addition, we may have to make contingent payments of \$4.8 million over four years in connection with the purchase of our Charleston, South Carolina manufacturing facility, based on the level of manufacturing revenues at this facility. At December 31, 2003 these contingent payment obligations, including the contingent payments due in connection with the acquisition of the M.V.I. and Aquasol product lines, had not been recorded as a liability on our consolidated balance sheet.

On August 7, 2003 we received a letter from the staff of the Enforcement Division requesting voluntary production of certain documents. We responded to this letter on August 21, 2003 and supplemented our response on August 29, 2003.

Independent of the August 7, 2003 inquiry letter, on September 26, 2003, certain members of our board and management voluntarily met with, and provided documents to, the staff of the Enforcement Division. As a follow-up to this September 26, 2003 meeting and as part of the inquiry initiated on August 7, 2003, on October 8, 2003, we received a further request from staff of the Enforcement Division for voluntary production of certain documents, to which we responded on October 30, 2003.

On January 14, 2004 and April 26, 2004, we received letters from the SEC's Division of Corporate Finance commenting on, asking questions about, and seeking additional disclosure with respect to certain of our periodic reports. We have responded to these letters.

In April 2004, in connection with an investigation conducted by the U.S. Attorneys Office, we received five federal grand jury subpoenas for document production and potential testimony related to, among other things, certain transactions regarding our 2002 and 2003 financial information, the terms, conditions of employment and compensation arrangements of certain of our senior management personnel, compensation and incentive arrangements for employees responsible for the sale of our Brethine, Darvocet, calcitriol, azathioprine and Darvon Compound products, quantities of the foregoing products in distribution channels, financial benefits with respect to specified corporate transactions to our senior management and others, certain loans obtained by us, extensions of credit, if any, by us to officers or directors, accounting for sales and returns of our foregoing products, our analysts' conference calls on financial results, internal and external investigations of pharmaceutical product sales activities, and related matters. We have also been advised that the SEC has initiated an inquiry into at least the same issues investigated by the Special Committee. The U.S. Attorneys Office has advised that we may also receive a subpoena from the SEC.

We and the Special Committee have agreed to cooperate fully with the government investigations, and the Special Committee has agreed to share all results of its investigation with the SEC and the U.S. Attorneys Office. To that end, two meetings of our outside counsel with attorneys for the U.S. Attorneys Office and

the SEC have taken place and numerous documents as requested by these government agencies have been voluntarily produced. We are working to schedule a third meeting with the U.S. Attorneys Office and the SEC in July in order to provide additional information related to the Special Committee's investigation to these government agencies. We and the Special Committee intend to facilitate any interviews of our employees or officers that may be requested by these government agencies.

The Department of Justice, SEC and other government agencies that are investigating or might commence an investigation of aaiPharma could impose, based on a claim of fraud, material misstatements, violation of false claims law or otherwise, civil and/or criminal sanctions, including fines, penalties, and/or administrative remedies. If any government sanctions are imposed, which we cannot predict or reasonably estimate at this time, our business, financial condition, results of operations or cash flows could be materially adversely affected. These matters have resulted, and are expected to continue to result, in a significant diversion of management's attention and resources and in significant professional fees.

On January 2, 2004, we received separate letters from the Kentucky Office of Attorney General and the Florida Office of Attorney General advising that each was currently investigating allegations regarding our pricing practices related to our average manufacturer price and best price calculations that are used by the government to set Medicaid reimbursement rates. Neither letter requested that we provide any information, and each letter merely requested that we retain all documents with respect to these calculations pursuant to a newly adopted federal regulation that would have permitted the destruction of these documents three years after the applicable prices were reported, except to the extent we were aware of an ongoing investigation. It is our understanding that many other pharmaceutical companies received similar letters at that time from attorneys general in a number of states and that such letters may have been in response to the new federal regulation that would have otherwise allowed the destruction of documents reflecting these pricing calculations. A number of attorneys general, including the Florida and Kentucky attorneys general, petitioned the U.S. Secretary of Health and Human Services to withdraw the new regulation. We are not aware of any further developments in these investigations.

We and certain of our officers have been named as defendants in purported shareholder class action lawsuits alleging violations of federal securities laws. These lawsuits were filed beginning in February 2004 and are pending in the U.S. District Court for the Eastern District of North Carolina. These lawsuits assert claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of our common stock during the period from January 31, 2002 through and including March 1, 2004. The complaints allege generally that the defendants knowingly or recklessly made false or misleading statements during the Class Period concerning our financial condition and that our financial statements did not present our true financial condition and were not prepared in accordance with generally accepted accounting principles. The complaints seek certification as a class action, unspecified compensatory damages, attorneys' fees and costs, and other relief. By order dated April 16, 2004, the district court consolidated the securities lawsuits into one consolidated action. We expect that the plaintiffs will file a consolidated, amended complaint later in 2004, to which we will respond in lieu of responding to the individual complaints.

In addition, we, one of our former officers, certain of our employees and others have been named in a purported class action brought by an aaiPharma retirement plan participant and beneficiary asserting claims under ERISA on behalf of a class of all persons who are or were participants or beneficiaries of the aaiPharma Inc. Retirement and Savings Plan during the period from April 24, 2002 to March 31, 2004. The complaint, which is pending in the U.S. District Court of the Eastern District of North Carolina, alleges generally that the defendants breached fiduciary duties owed under ERISA with respect to the investment of Plan assets in aaiPharma stock by misleading participants and beneficiaries of the Plan regarding our earnings, prospects, and business condition. The complaint seeks certification as a class action, unspecified compensatory damages, attorneys' fees and costs, and other relief.

These securities and ERISA lawsuits are at an early stage, and no lead plaintiff has yet been appointed, nor a consolidated amended complaint served, in the federal securities litigation. We are not required to file an answer or motion to dismiss in the federal lawsuits until after service of the consolidated amended complaint on us and no discovery has yet occurred in these lawsuits. By, and subject to, the terms of our bylaws, we have certain obligations to indemnify the current and former officers of the Company who have been named as defendants in these lawsuits. We have purchased directors and officers liability insurance that may provide coverage for some or all of these lawsuits and governmental investigations. There is a risk, however, that some or all of the claims or expenses will not be covered by such policies; or that, even if covered, our ultimate liability will exceed the available insurance. Although we intend to vigorously pursue all defenses available in these lawsuits, an adverse determination in these lawsuits or an inability to obtain payment under our D&O insurance policies for litigation and indemnification costs and any damages ultimately borne by us as a result of these lawsuits and investigations could have a material adverse effect on our business, financial condition, results of operations or cash flows.

We are a party to a number of legal actions with generic drug companies. We are involved in four lawsuits centered on our omeprazole-related patents, including one lawsuit brought by us against an alleged infringer of our patents and three lawsuits which were brought by third parties against us and are currently essentially inactive. Omeprazole is the active ingredient found in Prilosec, a drug sold by AstraZeneca.

Two omeprazole-related cases have been filed against us by Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. in the U.S. District Court for the Southern District of New York in July 2001 and November 2001. The plaintiffs in these cases have challenged the validity of five patents that we have obtained relating to omeprazole and are seeking a declaratory judgment that their generic form of Prilosec does not infringe these patents. Additionally, they have alleged misappropriation of trade secrets, tortious interference, unfair competition and violations of the North Carolina Unfair Trade Practice Act. We have denied the substantive allegations made in these cases.

Both of these cases against us are in early stages of litigation. However, while these plaintiffs have sought approval from the FDA to market a generic form of Prilosec, no such FDA approval has, as of March 14, 2004, been granted to them. In addition, these plaintiffs' omeprazole product has been found in separate litigation to infringe certain patents of AstraZeneca and the infringement findings have been upheld on appeal. These lawsuits are essentially inactive at this time. Only limited discovery has occurred in these lawsuits and no additional discovery is currently being sought. No date has been set for trial. In the event that these lawsuits again become active, we intend to vigorously defend the patents' validity and to determine whether or not Dr. Reddy's product infringes any of our relevant patents.

The third case involving our omeprazole patents was brought against us in August 2001 by Andrx Pharmaceuticals, Inc. in the U.S. District Court for the Southern District of New York. Andrx has challenged the validity of three of our omeprazole patents and has also sought a declaratory judgment that its generic omeprazole product does not infringe these patents. Furthermore, Andrx claims violations of federal and state antitrust laws with respect to the licensing of these omeprazole patents and has sought injunctive relief and unspecified treble damages. We have denied the substantive allegations made by Andrx.

This case is in an early stage of litigation. While Andrx has received FDA approval for its generic omeprazole product, to our knowledge, it is not currently marketing this drug in the U.S. following a judicial finding that Andrx's omeprazole product infringed certain AstraZeneca patents, which findings have been upheld on appeal. No date has been set for trial. No discovery is currently being sought. We have filed a motion to dismiss the litigation on various grounds and Andrx has objected to our motion. The

lawsuit is essentially inactive at this time. As of June 1, 2004, the judge has not decided our motion to dismiss the litigation.

The fourth case involving our omeprazole patents was brought in December 2002 by us against Kremers Urban Development Co., Schwarz Pharma Inc. and Schwarz Pharma AG (collectively, together with the other named defendants, "KUDCO") in the U.S. District Court for the Southern District of New York. KUDCO has a generic omeprazole product with final FDA marketing approval, was found not to infringe the AstraZeneca patents in the separate AstraZeneca patent litigation, and is currently selling its generic substitute for Prilosec in the U.S. marketplace.

Discovery is continuing at this time. The parties previously had agreed to the commencement of the trial in January 2005 but have recently moved the trial date to June 2005.

In cases where we have initiated an action, we intend to prosecute our claims to the full extent of our rights under the law. In cases where we are named defendants, we intend to vigorously pursue all defenses available.

In 2003, we entered a three-year services agreement with Athlon Pharmaceuticals to provide sales support in designated territories throughout the United States for the Darvocet A500 product. As of December 31, 2003, future minimum payments due under this agreement were: \$14.4 million--2004; \$14.4 million--2005; \$10.8 million--2006; and zero--thereafter. Subsequent to the commercial launch of Darvocet A500 in October 2003, issues have arisen with respect to the level of performance by this contract sales force. We have commenced legal action against Athlon alleging breach of our agreement and seeking a declaratory judgment that we are entitled to terminate this agreement and injunctive relief and damages and have terminated this agreement. We may not be successful in this action. Athlon has asserted several counterclaims, including breach of an implied covenant of good faith in fair dealing and anticipatory breach of the contract. We have filed a reply denying these allegations.

In addition, in 2003, we entered into a multi-year supply agreement for Darvocet A500. As of December 31, 2003, the minimum guaranteed purchase requirement remaining under this agreement was \$12.9 million. We have amended this agreement to allow additional products of ours to be manufactured by the party to this supply agreement and for these products to count against our minimum purchase obligation, though we have not established any terms, including pricing, with respect to the manufacture of these additional products.

The following schedule summarizes contractual obligations and commitments at December 31, 2003 (in thousands):

	Less Than One Year	One Year Through Three Years	Over Three Through Five Years	Over Five Years	Total
Long-term debt	\$ 4,000	\$ 40,000	\$ 120,000	\$ 175,000	\$ 339,000
Operating leases	7,654	11,401	9,177	7,257	35,489
Sales support commitments	14,400	25,200	-	-	39,600
Capital lease obligations	323	408	-	-	731
Purchase commitments	<u>28,846</u>	<u>8,600</u>	<u>-</u>	<u>-</u>	<u>37,446</u>
	<u>\$ 55,223</u>	<u>\$ 85,609</u>	<u>\$ 129,177</u>	<u>\$ 182,257</u>	<u>\$ 452,266</u>

Our purchase commitments are primarily related to outstanding orders and commitments with suppliers to purchase finished goods related to our pharmaceutical products.

Our liquidity needs increased during 2003, and our annual net interest expense may exceed \$28 million in 2004. We have an interest payment on the senior subordinated notes of \$10.1 million due in October 2004.

We and certain of our current and former officers and employees have been named as defendants in multiple purported class action lawsuits commenced by stockholders and participants in our employee benefit plans beginning in February 2004 alleging violations of federal securities and pension laws. In addition, in April 2004, we received subpoenas for document production and potential testimony issued by a grand jury of the U.S. District Court for the Western District of North Carolina related to 2002 and 2003 financial information and other matters. We have also been advised by the Office of the United States Attorney for the Western District of North Carolina that we may receive a subpoena from the SEC. Our legal and other related costs in connection with these proceedings will further increase our liquidity needs in 2004.

We will incur substantial non-ordinary cash expenses in 2004, resulting from the cost of consultants, such as FTI Consulting and other professional consultants performing services related to the Special Committee's investigation. In addition, we will continue to incur significant professional fees related to the government investigations, class action lawsuits and other litigation.

On March 31, 2004, each of Moody's Investors Service and Standard & Poor's Ratings Services announced that it had lowered our corporate credit rating: Moody's to Caa2 from B2 and Standard & Poor's to CCC from B+. At the same time, Moody's lowered its rating of our senior subordinated notes to Ca from Caa1 and our senior unsecured issuer rating to Caa3 from B3. Standard & Poor's lowered its senior secured debt rating to CCC+ from BB-, and its subordinated debt rating to CC from B-. These actions may negatively affect our ability to raise necessary capital through debt securities or other debt instruments on acceptable terms, or at all.

Analysis of Liquidity

We believe, subject to the conditions and contingencies described above, that our cash flow from operations, and borrowing capacity under our new senior credit facilities will be adequate to meet our needs for working capital and anticipated capital expenditures. We are exploring the sale of certain non-revenue generating assets to supplement our cash flow and to facilitate the availability of cash to coincide with anticipated cash needs. Sales of assets above specific thresholds will require the consent of the lenders under our senior credit facilities.

If results of operations do not meet our forecasts, our actual cash flow from operations may be less than we anticipate. In addition, in those circumstances covenant violations under our senior credit facilities could occur. The financial covenants in the senior credit facility include a maximum senior debt to EBITDA (as defined) leverage ratio of 2.40x for 2004, which declines on a scheduled basis in quarterly periods thereafter, and a minimum EBITDA to fixed charges ratio of 1.15x for 2004, which escalates in increments in each quarterly period thereafter. The financial covenants also require a minimum of \$16,000,000 of Consolidated Net Operating Cash Flow (as defined) for the periods from (i) April 23, 2004 through May 29, 2004 (with a cure of any default if the \$16,000,000 figure is achieved from April 23, 2004 through June 10, 2004), and (ii) April 23, 2004 through June 30, 2004 (with a cure of any default if the \$16,000,000 figure is achieved from April 23, 2004 through July 14, 2004). The senior credit facilities also require a minimum level of unrestricted cash and/or availability under the revolving credit portion of the facilities, after taking into account reductions for certain overdue trade payables. The covenant levels under our senior credit facilities were set based upon our then-current forecasts, and we can give no assurance that our actual results of operations will be consistent with these forecasts.

If we violate covenants under our senior credit facilities, we would seek waivers and amendments from our lenders, but we can give no assurance that any such necessary waivers and amendments would be available

at all or on acceptable terms. If we were unable to obtain a waiver of future covenant violations, the lenders would be entitled to require immediate repayment of all amounts outstanding under the senior credit facilities. An acceleration of outstanding amounts under the senior credit facilities would also cause a default under, and could permit acceleration of, our senior subordinated notes due 2010. In the event of one or more such defaults, the Company may seek additional sources of financing or access to the capital market, although there can be no assurance that either source will be available on terms acceptable to us or at all.

Impact of Recent Events on 2004 Results

Recent developments will have a significant impact on our results of operations in 2004 and future periods. As a result of the refinancing of our senior credit facilities in April 2004, we will record an expense of approximately \$6.2 million in the second quarter of 2004. The M.V.I. and Aquasol Sale resulted in a significant gain that we will record in the second quarter of 2004.

As noted above, we believe that as of December 31, 2003, wholesaler inventory levels of our Brethine injectable and Darvocet N-100 products exceeded target levels. These wholesaler inventory levels may adversely affect our sales of these products in 2004 until wholesaler inventories decline to appropriate levels. The recent approvals of generic versions of our Brethine injectable product will further reduce sales of this product. In addition, although Darvocet A500 is not subject to competition of products approved by the FDA as generic versions of Darvocet A500, the substitution by pharmacists in some jurisdictions of generic versions of Darvocet N-100 or other similar products for prescriptions written for Darvocet A500, is likely to result in sales of this product being below our initial expectations. As a result, sales of this line extension product may not materially stem the current trend of declining unit sales of our Darvon/Darvocet products.

As a result of our acquisition of the New Pain Products in December 2003, our amortization of acquired product intangible assets, a component of direct costs of product sales, will increase by approximately \$4.5 million in 2004 compared to 2003, absent any product line acquisitions or subsequent product line sales in 2004. The M.V.I. and Aquasol Sale, completed in April 2004, will not affect amortization of acquired product rights in 2004 because the intangible assets associated with the M.V.I. and Aquasol product line had indefinite lives. Expenses for professional fees will be materially greater in 2004 than 2003 as a result of fees paid to our consultants, including FTI Consulting, the expenses associated with the Special Committee's investigation, fees and expenses related to the solicitation of consents from holders of our senior subordinated notes, which was completed in April 2004, and fees and expenses related to pending litigation, including the pending federal securities litigation, and governmental investigations.

Based in part on the matters described above, we anticipate that the Company will report a loss for each of the first two quarters of 2004.

Management Changes

On February 12, 2004, we announced that David Hurley, our Chief Operating Officer, was leaving aaiPharma, effective immediately.

On March 29, 2004, we announced that Dr. Frederick D. Sancilio, the founder of our company and our Executive Chairman and Chief Scientific Officer, would replace Dr. Philip S. Tabbiner as our Chief Executive Officer. Dr. Tabbiner also resigned from our board of directors to take a consulting position with aaiPharma for fifteen months to facilitate this transition.

On May 11, 2004, we announced that William L. Ginna, Jr., our Chief Financial Officer, had left the Company. Mr. Ginna has taken a consulting position with aaiPharma for twelve months to assist the Company when needed.

In March 2004, we appointed Gregory F. Rayburn, a senior managing partner at FTI Consulting, to the position of interim Chief Operating Officer. In May 2004, we appointed Gina Gutzeit, a senior managing partner at FTI Consulting, to the position of interim Chief Financial Officer.

Critical Accounting Policies

Revenue Recognition

We recognize revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" as amended by Staff Accounting Bulletin No. 104 (together, "SAB 101") and Statement of Financial Accounting Standards No. 48 "Revenue Recognition When Right of Return Exists" ("FAS 48"). SAB 101 states that revenue should not be recognized until it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. FAS 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if (1) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated.

Net Revenues. Our net revenues represent our total revenues less allowances for customer credits, including estimated discounts, rebates, chargebacks, product returns and non-research and development expenses reimbursed by customers.

The following table sets forth our gross revenues and the amount of dilution to revenues resulting from allowances for customer credits, including discounts, rebates, chargebacks, product returns and other allowances for each of 2003, 2002 and 2001:

	Years Ended December 31,		
	2003	2002 (as restated) (in thousands)	2001
Gross revenues	\$ 327,282	\$ 283,914	\$ 150,115
Allowance for customer credits	<u>102,305</u>	<u>53,404</u>	<u>9,042</u>
Net revenues	<u>\$ 224,977</u>	<u>\$ 230,510</u>	<u>\$ 141,073</u>

Net revenues are reported for our three operating segments, which are product sales, development services and product development.

Product Sales. We recognize revenues for product sales at the time title and risk of loss are transferred to the customer, and the other criteria of SAB 101 and FAS 48 are satisfied. Product shipping and handling costs are included in cost of sales. We accept returns of products near their expiration date.

At the time we recognize revenue from product sales, we record an adjustment, or decrease, to revenue for estimated chargebacks, rebates, discounts and returns. Revenue reserves are established on a product-by-product basis. These revenue reductions are established by management as its best estimate at the time of sale based on each product's historical experience adjusted to reflect known changes in the factors that impact such reserves. Reserves for chargebacks, rebates and discounts are established based on the contractual terms with our customers; analysis of historical levels of discounts, chargebacks and rebates; communications with customers and purchased information about the rate of prescriptions being written and the levels of inventory remaining in the distribution channel as well as our expectations about the market for each product and anticipated introduction of competitive products. The reserve for chargebacks is the most significant estimate used in the recognition of our revenue from product sales. In brief, we have established contract prices for certain indirect customers that are supplied by our wholesale customers. A chargeback represents the difference between the current published wholesale acquisition cost and the indirect customers' contract prices.

Prior to 2003, the amount of actual product returns experienced by the Company had not been significant. As a result, actual returns were charged against revenue in the period they occurred and aggregate revenue reserves were evaluated quarterly to determine if they were sufficient to cover estimated chargebacks, rebates and related allowances, as well as the expected rate of returns, and adjusted as deemed necessary. In 2003, we began segregating our products return reserve, which prior thereto we believed was adequately covered by our aggregate revenue reserves for chargebacks, rebates and related allowances. We increased the level of detail included in our analyses to include analyzing inventory in the channel to determine remaining shelf life. Our returns reserve needs are primarily related to the number of months of inventory estimated to be in the distribution channel. Levels of inventory in the distribution channel are monitored and estimated based on information we purchase from the wholesalers, combined with active discussions between our sales personnel and the wholesalers we supply. In addition, our actual sales, returns and chargeback history are used to assess the reasonableness of the estimated number of months of inventory on hand at our wholesalers. The shelf life of products remaining in the distribution channel is estimated based on an analysis of each lot sold. Each batch has a specific expiration date. A review of the actual returns history is performed and the run rate of sales out of the distribution channel is estimated. Estimated product returns reserves are adjusted based on these reviews. Reserves may also be adjusted to reflect any significant changes in trends or based upon new information that we believe may affect the reserve needs. Allowances for new product introductions are estimated based on our experiences for similar products that we currently market and are adjusted as deemed necessary based on our experience with each product. Our reserve analysis also includes a review for the potential introduction of generic competition and the resulting impact on pricing and returns reserves. Existing reserves may be adjusted accordingly to reflect our estimate for any impact these factors may have. We continually monitor our assumptions with respect to our revenue reserves for product sales and modify them if necessary.

In 2003, we initially recorded net revenues from the sale of newly launched products at the time of shipment to wholesalers. We have subsequently determined, however, that not all of the conditions for recognition of revenue specified by SFAS 48 were met. In addition, we have determined that sales of our Brethine product to a specialty wholesaler did not satisfy the condition of SFAS 48 for the sales of these products. The new product launches and the sale of Brethine to a specialty wholesaler have been recorded under the consignment model. Under the consignment model, we do not recognize revenue upon shipment of product to wholesalers, but instead invoice the wholesaler, record deferred revenue at gross invoice sales price and classify the inventory held by the wholesaler as consignment inventory at our cost of such inventory. We recognize revenue when such inventory is sold through to the wholesalers' customers, on a first-in first-out (FIFO) basis.

Product Development. Product development revenues consist of royalty revenues and licensing fees. We recognize royalty revenues as earned based on sales of the underlying products. Each of our licensing agreements is reviewed to determine the appropriate revenue recognition treatment under SAB 101. Revenues

from upfront licensing fees are deferred and amortized over the term of the associated agreement or as ongoing services are performed. Revenues resulting from achieving certain milestones stipulated in our agreements are recognized when the specific milestone is achieved. Milestones are based upon the occurrence of a substantive element specified in the contract or as a measure of substantive progress towards completion under the contract.

Development Services. We recognize the majority of our development services revenues from fee-for-service contracts on a proportional performance basis as the work is performed. This is based on the ratio of actual direct costs incurred to total estimated direct contract costs, which is the best indicator of performance of these contract obligations. This ratio is multiplied by the estimated contract value to determine the revenue to be recognized. The proportional performance method requires us to estimate total expected revenue, costs and profitability of the contract. These estimates are reviewed periodically and, if these estimates change or actual results differ from expected results, an adjustment is recorded in the period in which they become reasonably estimable. These adjustments could have a material effect on our results of operations. Historically, there have not been significant variations between contract estimates and actual costs incurred which were not recoverable from clients. Changes in the scope of work generally result in an amendment to contract pricing terms. Amended contract amounts are not included in net revenues until earned and realization is assured. We also recognize revenue on a time and materials basis in accordance with the specific contract terms. Revenues recognized prior to contract billing terms are recorded as work in progress. Provisions for losses on contracts, if any, are recognized when identified. Clients generally may terminate services at any time, however the majority of our contracts contain provisions that require payment for all services rendered to date, even those services that have not yet been billed. We perform ongoing credit evaluations of our customers and maintain reserves for potential uncollectible accounts. Actual losses from uncollectible accounts have been minimal.

Intangibles Assets

When we acquire the rights to manufacture and sell a product, we record the aggregate purchase price, along with the value of the product related liabilities we assume, as intangible assets. We use the assistance of valuation consultants to help us allocate the purchase price to the fair value of the various intangible assets we have acquired. Then, we must estimate the economic useful life of each of these intangible assets in order to amortize their cost as an expense in our statement of operations over the estimated economic useful life of the related asset. The factors that drive the actual economic useful life of a pharmaceutical product are inherently uncertain, and include physician loyalty and prescribing patterns, competition by products prescribed for similar indications, future introductions of competing products not yet FDA approved, the impact of promotional efforts and many other issues. We use all of these factors in initially estimating the economic useful lives of our products, and we also continuously monitor these factors for indications of appropriate revisions.

In assessing the recoverability of our intangible assets, we must make assumptions regarding estimated undiscounted future cash flows and other factors. If the estimated undiscounted future cash flows do not exceed the carrying value of the intangible assets we must determine the fair value of the intangible assets. If the fair value of the intangible assets is less than its carrying value, an impairment loss will be recognized in an amount equal to the difference. If these estimates or their related assumptions change in the future, we may be required to record impairment changes for these assets. In addition, material adjustments to our forecasted revenues from the sales of any of our acquired product lines including Brethine and Darvocet may require us to employ different assumptions with respect to our estimated cash flows. We review intangible assets for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If we determine that an intangible asset is impaired, a non-cash impairment charge would be recognized.

For the years ended December 31, 2001 and 2000, goodwill, defined as the excess of the purchase price over the fair value of the net assets of acquired businesses, was amortized over 20 years. In accordance with SFAS 141, we ceased amortization of goodwill as of January 1, 2002. For purchase business combinations consummated subsequent to June 30, 2001, goodwill and indefinite-lived intangible assets are not amortized, but are evaluated for impairment on an annual basis or as impairment indicators are identified. Other identifiable intangible assets are amortized, if applicable, on a straight-line basis over their estimated useful lives, which range from 3 to 20 years.

Our goodwill and intangible assets consist of the following:

	December 31, 2003	December 31, 2002 (as restated)
	(in thousands)	
Goodwill, net	\$ 13,361	\$ 11,378
Intangible assets, net:		
Definite-lived	\$ 320,530	\$ 241,018
Indefinite-lived	51,017	51,017
	<u>371,547</u>	<u>292,035</u>
Less accumulated amortization	(20,232)	(10,366)
	<u>\$ 351,315</u>	<u>\$ 281,669</u>

On a periodic basis, or as otherwise required, we assess the value of our goodwill, intangibles and other assets by determining their ability to recover the unamortized balances over the remaining useful lives. Goodwill, intangibles and other long-lived assets determined to be unrecoverable would be written off in the period in which such determination is made.

Set forth in the table below are the details of the purchase price allocations for of our all major product line acquisitions since the beginning of 2001. The table lists the assets, the value allocated to each asset, how the value was determined, and the useful life assigned to each asset. In these acquisitions, the only tangible assets acquired were inventory and marketing/promotional materials, which were valued based on internal analyses and data provided by the sellers. Inventory obtained at time of acquisition was valued at the estimated selling price less the cost of disposal and a reasonable selling profit. Marketing/promotional materials received were generally outdated and in limited quantities, so no material value was assigned to them in the purchase price allocations. We engaged third-party valuation consultants to assist in purchase price allocations, including identification of intangible assets, recommendations of fair value of intangible assets, and determination of expected lives of those assets. Intangible assets that arose from contractual or legal rights and other intangible assets that were separable, as provided in paragraph 39 of SFAS 141, were identified. Among the assets that were considered for recognition were trademarks, Internet domain names, non-competition agreements, customer lists, backlogs, customer contracts and non-contractual relationships, licensing and royalty agreements, supply contracts, employment contracts, patented and unpatented technology, and trade secrets.

The third-party valuation consultants reviewed pertinent facts and recommended for each asset the appropriate generally accepted valuation approach and methodology from among the cost, market, and income approaches. Where possible, a valuation derived using an alternative valuation approach or

methodology was presented and used by management to evaluate the reasonableness of the recommended fair value.

<u>Identifiable Assets</u>	<u>Value (in millions)</u>	<u>How Valued</u>	<u>Useful Life</u>
M.V.I. and Aquasol (as restated)			
Total purchase price, including transaction fees	<u>\$ 54.7</u>		
<u>Allocation of purchase price:</u>			
Inventory	\$ 3.7	Estimated Selling Price Less Cost of Disposal and a Reasonable Selling Profit	N/A
Trademarks	27.3	Income Approach Discounted Cash Flow Method	Indefinite
Developed Technology	<u>23.7</u>	Income Approach Discounted Cash Flow Method	Indefinite
Total	<u>\$ 54.7</u>		
Brethine (as restated)			
Total purchase price, including transaction fees	<u>\$ 26.6</u>		
<u>Allocation of purchase price:</u>			
Trademarks-Existing	\$ 11.3	Income Approach Discounted Cash Flow Method	20 years
Trademarks-Reformulated	9.4	Income Approach Discounted Cash Flow Method	20 years
Developed Technology	<u>5.9</u>	Income Approach Discounted Cash Flow Method	20 years
Total	<u>\$ 26.6</u>		

<u>Identifiable Assets</u>	<u>Value (in millions)</u>	<u>How Valued</u>	<u>Useful Life</u>
Darvon/Darvocet (as restated)			
Total purchase price, including transaction fees	<u>\$ 212.6</u>		
<u>Allocation of purchase price:</u>			
Inventory	\$ 1.7	Estimated Selling Price Less Cost of Disposal and a Reasonable Selling Profit	N/A
Trademarks-Existing	80.3	Income Approach Discounted Cash Flow Method	20 years
Trademarks-Reformulated	50.3	Income Approach Discounted Cash Flow Method	20 years
Developed Technology	<u>80.3</u>	Income Approach Discounted Cash Flow Method	20 years
Total	<u>\$ 212.6</u>		
Elan Pain Portfolio			
Total purchase price, including transaction fees	<u>\$ 103.4</u>		
<u>Allocation of purchase price:</u>			
Inventory	\$ 5.1	Estimated Selling Price Less Cost of Disposal and a Reasonable Selling Profit	N/A
Trademarks	49.1	Income Approach Discounted Cash Flow Method	20 years
Developed Technology	<u>49.2</u>	Income Approach Discounted Cash Flow Method	20 years
Total	<u>\$ 103.4</u>		

Inventories

Our inventories are valued at the lower of cost (determined on a first-in, first-out basis) or market. We review our inventory for short dated or slow-moving product and inventory commitments under supply agreements based on projections of future demand and market conditions. For inventory so identified, we estimate market value or net sales value based on current realization trends. If the projected net realizable value is less than cost, on a product basis, we provide a reserve to reflect the lower value of that inventory. We recognize inventory losses at the time such losses are evident rather than at the time products are actually sold. We also maintain supply agreements with some of our vendors which contain minimum purchase requirements. We estimate future inventory requirements based on current trends. If our estimated future inventory requirements exceed estimated shipments to our customers, we record a charge in direct costs. If we over- or under-estimate the amount of inventory that will not be sold prior to expiration, there may be a material adverse impact on our consolidated financial condition and results of operations.

Income Taxes

Income taxes are provided for under the liability method. This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of differences between the tax basis of assets or liabilities and their carrying amounts in the consolidated financial statements. A valuation allowance is provided for deferred tax assets if it is more likely than not that these items will either expire before we are able to realize their benefit or if future deductibility is uncertain. Developing the provision for income taxes requires significant judgment and expertise in federal and state income tax laws, regulations and strategies, including the determination of deferred tax assets and liabilities and, if necessary, any valuation allowances that may be required for deferred tax assets. Our judgments and tax strategies are subject to audit by various taxing authorities. While we believe we have provided adequately for our income tax liabilities in our consolidated financial statements, adverse determinations by these taxing authorities could have a material adverse effect on our consolidated financial condition and results of operations.

Research and Development Arrangements

Research and development expense was 10% of our net revenues in 2003, and we expect research and development activities to account for between 8% and 10% of budgeted annual net revenues in 2004. The following product development table identifies, for each of our major development programs in 2003, the stage of development at December 31, 2003 of the lead product or products in each program, research and development spending on each program in 2003, cumulative research and development spending on each program from inception through December 31, 2003, an estimate of the additional research and development expense to complete the development of the lead product in the program, and the year in which we anticipate completing the lead product in the program. The estimated additional expense to complete the lead product and the timing of completion represent our estimates. As we continue these development programs and evaluate our interim results and other information, we may decide to change the scope and direction of a program and we may change how we allocate our research and development spending to pursue more promising product candidates. In addition, our actual costs in developing these products may be materially different from our estimates due to uncertainties inherent in product development. Moreover, because of these inherent uncertainties, we may not be able to successfully develop, commercialize or license the products or technologies included in the table within the time periods specified, if at all.

Major Development Program (and Lead Products)	Stage of Development for Lead Products in Program	2003 Program R&D Spending (1)	Cumulative Program R&D Spending Through December 31, 2003	Estimated Additional R&D Spending to Complete Lead Products	Estimated Year of Completion of Lead Products
(dollars in millions)					
Products:					
Pain Management (Darvocet line extension)	Pre-clinical	\$ 12.2	\$ 27.6	\$ 2.1	2005
(ProSorb-D)	Phase III			4.5	2005
Gastrointestinal (GI-1)	Phase I	4.2	16.3	4.9	2006
Critical Care (Brethine line extension)	SNDA filed in June 2003 (2)	2.6	5.2	0.1	2004
Other	n/a	3.0	n/a	n/a	n/a

Technologies:

Drug Delivery	0.2	13.9	
(Fexofenadine/ Pseudoephedrine)	NDA filed in December 2003 (3)		2004
	<u>\$</u>	<u>22.2</u>	

- (1) Includes an allocation of \$5.8 million of indirect costs, primarily management and administrative overhead and facilities costs, based on direct research and development costs in 2003. In addition, this includes an allocation of \$0.4 million reported as depreciation in our consolidated statement of operations.
- (2) Approved in 2004; awaiting commercialization.
- (3) This product is being developed for a customer pursuant to a development agreement. The customer filed the NDA.

In addition to the specifically identified programs named in the table, we have targeted additional product development programs or projects. These other programs or projects may require significant research and development spending in future periods.

There is a risk that any specific research and development program or project may not produce revenues. We believe that the potential profit margins from successful development programs or projects will compensate for costs incurred for unsuccessful projects. We are currently involved in many pharmaceutical and technology development programs or projects and believe that these activities help to diversify our portfolio and manage our risk. See "--Risk Factors and Forward-Looking Statements."

Related Party Transactions

In 1994, as part of our internal development program, we organized Endeavor Pharmaceuticals, Inc. to continue development of products that we had been developing on our own and to permit investors to directly invest in the development of these products. We assigned our rights to these products to Endeavor in return for approximately 47% of Endeavor's fully diluted equity. As a result of additional issuances of equity by Endeavor to third party investors, our fully diluted ownership interest in Endeavor has been reduced to approximately 13%. As of December 31, 2002, Dr. Frederick D. Sancilio, our Executive Chairman and Chief Scientific Officer, owned 0.8% of Endeavor's fully diluted equity and an affiliate of James L. Waters, one of our directors, owned 0.6%. We had net revenues for services provided to Endeavor at our standard rates of \$0.6 million in 2003, \$1.1 million in 2002 and \$0.2 million in 2001. We had no related accounts receivable at December 31, 2003 and \$0.3 million at December 31, 2002. In December 2003, Endeavor sold substantially all of its assets to a third party. As part of this transaction, we recorded a gain of \$1.8 million for the sale of our investment in Endeavor. This gain is included in other income on the consolidated statement of operations. Endeavor filed articles of dissolution in December 2003 with the Delaware Secretary of State.

We organized Aesgen, Inc. with an affiliate of the Mayo Clinic in 1994 and funded it in 1995 with an affiliate of the Mayo Clinic, MOVA Pharmaceutical Corporation and certain other investors to combine our development capabilities with the medical expertise of the Mayo Clinic and to permit investors to directly invest in the development of these products. We distributed our initial common stock investment in Aesgen to our shareholders prior to our initial public offering in 1996. As a result, some of our directors, executive officers and holders of 5% or more of common stock who held our stock prior to the initial public offering, including Dr. Sancilio, beneficially own common equity of Aesgen. In the aggregate they own approximately 15% of Aesgen's fully diluted common equity. In October 2001, we agreed to provide development services

to Aesgen, through AAI Development Services, at our standard rates in exchange for \$1.1 million of Aesgen convertible preferred stock. Through December 31, 2003, we had performed \$580,000 of services under this agreement. At December 31, 2003, we held convertible preferred shares of Aesgen that represented 10.0% of Aesgen's fully diluted common equity, which included 5.4% earned through December 31, 2003, for services performed under this agreement. We do not anticipate performing any additional services for Aesgen under this agreement.

In December 2001, we acquired rights, title and interest to some of the products being developed by Aesgen. These products include five products for which abbreviated new drug applications have been approved by the FDA, and two other products under development. As consideration for the purchase of these products, we waived all claims to amounts due from Aesgen. At December 31, 2003, the book value of these assets was zero.

In February 2002, we purchased a generic calcitriol product from Aesgen for payment of \$1.0 million in cash and additional contingent milestone payments of up to \$1.5 million. In 2003, the prerequisite for payment of an additional \$500,000 of such contingent milestones occurred and such payment was made to Aesgen, while the prerequisites for payment of the remaining \$1.0 million were not met and no further payment of this amount is owed by us. Under this agreement, we are obligated to pay royalty payments for the eight-year period following the first commercial sale of this product. In 2003, we expensed royalties related to Aesgen of \$0.6 million. Of this amount, none was payable at December 31, 2003.

We recognized net revenues of zero, \$494,000 and \$86,000 from Aesgen for the years ended December 31, 2003, 2002 and 2001, respectively. We had no related accounts receivable or work-in-progress at December 31, 2002 or 2001.

See Note 8 to our Consolidated Financial Statements included elsewhere in this report for a more detailed description of these related party transactions.

Inflation

We believe that the effects of inflation generally do not have a material adverse effect on our consolidated results of operations or financial condition.

New Accounting Standards

In 2003, we adopted Statement of Financial Accounting Standards No. 145, "Rescission of FASB Statements 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" ("SFAS 145"). SFAS 145 no longer requires companies to report gains or losses associated with the extinguishment of debt as a component of extraordinary gains or losses, net of tax. In addition, any extraordinary gains or losses on extinguishment of debt in prior periods presented would require reclassification. As required by SFAS 145, the extraordinary loss recognized in the year ended December 31, 2002 of approximately \$8.1 million (\$5.3 million net of tax) to record the write-off of deferred financing and other costs related to its prior debt facilities has been reclassified to other expense.

Statement of Financial Accounting Standards No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"), requires that a liability for costs associated with an exit or disposal activity be recognized when the liability is incurred rather than when a commitment to an exit plan is made. SFAS 146 is effective for exit or disposal activities that are initiated after December 31, 2002. Adoption of this statement did not have a material effect on our financial position or results of operations.

In January 2003, the Financial Accounting Standards Board issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities" (FIN 46). FIN 46, as amended, requires that variable interest entities be consolidated by the primary beneficiary of the entity if certain criteria are met. FIN 46 is effective immediately for all variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 became effective for us during the fourth quarter of 2003. Based upon our review, we have not identified any entity that would require consolidation. Provided that we are not the primary beneficiary, the maximum exposure to losses related to any entity that may be determined to be a variable interest entity is limited to the carrying amount of the investment in the entity.

We do not believe the other recently issued, but not yet effective, accounting standards will have a material impact on the Company.

Risk Factors and Forward Looking Statements

Risks Related to our Financial Condition.

We have substantial future cash needs and potential cash needs and we cannot assure you that we will be successful in generating or otherwise obtaining the funds necessary to meet those needs.

We estimate that we have sufficient cash, liquid resources and realizable assets and investments to meet our near-term liquidity requirements. In making this estimate, we have not assumed any material payments in connection with our pending litigations in the near term, other than anticipated professional fees. Any material adverse legal judgments, fines, penalties or settlements arising from our pending litigations or investigations could require us to obtain additional funds. Although we expect to incur a loss in each of the first two quarters of 2004, in making our liquidity estimates, we have also assumed a certain level of operating performance. Our future operating performance will be affected by the factors discussed in this report and other factors, many of which are beyond our control. If our future operating performance is less than anticipated, we could be required to increase cash flow by selling assets and/or reducing staffing levels to improve liquidity. We cannot assure you that we would be able to sell assets on commercially reasonable terms, or at all, or that reductions in our staffing levels would alleviate short-term liquidity issues or would not be disruptive to our business. We could also be required to obtain additional funds. As described below, certain events, including our inability to incur additional indebtedness under the restrictive covenants contained in our existing debt instruments, have materially adversely affected our financial flexibility, including our ability to access external sources of capital to finance our business. If our estimates are incorrect and we are required to obtain additional funds, we cannot assure you that we would be able to obtain those funds on commercially reasonable terms, or at all, which would have a material adverse effect on our business, financial condition, results of operations and liquidity.

Our substantial indebtedness may severely limit cash flow available for our operations and could impair our ability to service debt or obtain additional financing if necessary.

We are highly leveraged. As of May 31, 2004, we have outstanding \$125 million in senior term loans and letters of credit of approximately \$280,000, as well as a senior revolving credit facility in the amount of \$15 million. In addition we have \$175 million of our senior subordinated notes outstanding. We have granted a first-priority lien on substantially all of our current and future property, including our intellectual property to secure our obligations with respect to our senior credit facilities and a second-priority lien on the same collateral to secure our subordinated notes.

The substantial amount of payments on our outstanding debt and other payment obligations could, among other things:

- limit our ability to obtain additional financing and acquire additional products,
- limit our flexibility in planning for, or reacting to, changes in our business and the industry,
- place us at a competitive disadvantage relative to our competitors with less debt,
- render us more vulnerable to general adverse economic and industry conditions; and
- require us to dedicate a substantial portion of our cash flow to service our debt.

Our ability to make future payments on, and, if necessary, to refinance our debt, will depend on our ability to generate cash in the future, which may be influenced by general economic, business, financial, competitive, legislative, regulatory and other factors beyond our control. We cannot assure you that our business will generate sufficient cash flow from operations or that future borrowings will be available in an amount sufficient to enable us to repay our debt on or before maturity. We may need to refinance all or a portion of our debt on or before maturity. We cannot assure you that we would be able to refinance any of our debt on commercially reasonable terms or at all.

Our near term liquidity and cash flow may be significantly affected by returns of product sold in 2003.

In 2003, we sold products to wholesalers on terms permitting the return of the product within six months if not then resold by the wholesaler, including approximately \$9 million of launch quantity Darvocet A500 sold in the second half of 2003. In addition, during the second half of 2003, we sold \$21 million of Brethine injectable to a specialty wholesaler and \$10.4 million of our Darvocet-N 100, 500 count bottles, to repackagers that resulted in wholesaler channel inventory levels significantly exceeding our target levels. In addition to the special return rights granted in product launches, each of our products may be returned to us near the expiration date of the product. If the wholesalers exercise their rights of return for these or other products, the issuance of either a credit on future sales or cash payment resulting from such returns could have a material effect on our liquidity in 2004. In addition, we are accounting for the shipments made to the specialty wholesaler under the consignment model. We received payment for these shipments in 2003. Thus, although we may record revenue in 2004 on the Brethine injectable product we sold in 2003, we will not receive any additional cash payments. Finally, to the extent that wholesaler channel inventories of our products exceed appropriate levels, as discussed above, our sales of those products in subsequent periods, and thus our cash flow, may be adversely affected.

Our reduced corporate credit ratings may impair our ability to effect future refinancings of our indebtedness or increase the expense of replacement indebtedness.

On March 31, 2004, Moody's and Standard & Poor's each announced reductions in our corporate credit ratings. These reductions of our credit ratings could adversely affect our ability to effect a future refinancing of our indebtedness or increase the cost of implementing any other debt financing.

Our failure to timely file our Annual Report on Form 10-K for the fiscal year ended December 31, 2003 could result in the delisting of our common stock on the NASDAQ Stock Market.

We received notice on March 30, 2004 from the NASDAQ Stock Market that, due to the delay in filing of our Form 10-K for the fiscal year ended December 31, 2003, we are not in compliance with certain NASDAQ marketplace rules and that our common stock would be subject to delisting at the opening of business on April 8, 2004, unless we request a hearing pursuant to NASDAQ rules. We requested and participated in a hearing before NASDAQ on April 29, 2004 in which we committed to filing this Report on

Form 10-K on or before June 15, 2004 and to file amended quarterly Reports on Form 10-Q for each of the three quarters of 2003 on or before June 30, 2004. On May 18, 2004 we received notice from the NASDAQ Stock Market that we were delinquent in filing our Quarterly Report on Form 10-Q for the first quarter of 2004. Even if we meet our commitments to file the periodic reports, the NASDAQ may still act to delist our stock from the NASDAQ Stock Market. Thereafter, our common stock would not be eligible for trading on any national securities exchange or the OTC Bulletin Board. If our common stock is no longer traded through a market system, it may not be liquid and we may be unable to obtain future equity financing, or use our common stock as consideration for mergers or other business combinations.

We have and in the near term will continue to incur significant professional fees which may materially negatively affect our cash flow.

We have incurred, and in the near term will continue to incur, significant professional fees in connection with the Special Committee's inquiry and in connection with pending litigation and governmental investigations. Our professional fees on a number of the matters, including the securities and ERISA litigation and governmental investigations, may extend for several years. These significant professional fees may materially negatively affect our results of operations and cash flow.

Customer concerns with respect to our liquidity and pending governmental investigations and litigation could make it difficult for us to obtain and retain long-term fee-for-service projects.

Some customers and potential customers of our AAI Development Services Division have expressed concern with respect to issues regarding our liquidity and pending governmental investigations and litigation in deciding whether to place long-term fee-for-service projects with us. If we are unsuccessful in overcoming these concerns, we may fail to obtain new long term fee-for-service projects, which would have a material adverse effect on our results of operations, financial condition and cash flow.

Risks Relating to Pending Governmental Investigations and Lawsuits

An adverse judgment in the securities and ERISA litigation in which we and certain current and former executive officers, employees and directors are defendants could have a material adverse effect on our results of operations and liquidity.

We and certain of our officers have been named as defendants in purported shareholder class action lawsuits alleging violations of federal securities laws. These lawsuits were filed beginning in February 2004 and are pending in the U.S. District Court for the Eastern District of North Carolina. These lawsuits assert claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of our common stock during the period from January 31, 2002 through and including March 1, 2004. The complaints allege generally that the defendants knowingly or recklessly made false or misleading statements during the Class Period concerning our financial condition and that our financial statements did not present our true financial condition and were not prepared in accordance with generally accepted accounting principles. The complaints seek certification as a class action, unspecified compensatory damages, attorneys' fees and costs, and other relief. By order dated April 16, 2004, the district court consolidated the securities lawsuits into one consolidated action. We expect that the plaintiffs will file a consolidated, amended complaint later in 2004, to which we will respond in lieu of responding to the individual complaints.

In addition, we, one of our former officers, certain of our employees and others have been named in a purported class action brought by an aaiPharma retirement plan participant and beneficiary asserting claims under ERISA on behalf of a class of all persons who are or were participants or beneficiaries of the aaiPharma Inc. Retirement and Savings Plan during the period from April 24, 2002 to March 31, 2004. The complaint alleges generally that the defendants breached fiduciary duties owed under ERISA with respect to

the investment of Plan assets in aaiPharma stock by misleading participants and beneficiaries of the Plan regarding our earnings, prospects, and business condition. The complaint seeks certification as a class action, unspecified compensatory damages, attorneys' fees and costs, and other relief.

These securities and ERISA lawsuits are at an early stage, and no lead plaintiff has yet been appointed, nor a consolidated amended complaint served, in the federal securities litigation. We are not required to file an answer or motion to dismiss in the federal lawsuits until after service of the consolidated amended complaint on us and no discovery has yet occurred in these lawsuits. By, and subject to, the terms of our bylaws, we have certain obligations to indemnify the current and former officers and employees of the Company who have been named as defendants in these lawsuits. We have purchased D&O insurance that may provide coverage for some or all of these lawsuits and governmental investigations. There is a risk, however, that some or all of the claims or expenses will not be covered by such policies; or that, even if covered, our ultimate liability will exceed the available insurance. Although we intend to vigorously pursue all defenses available in these lawsuits, an adverse determination in these lawsuits or an inability to obtain payment under our D&O insurance policies for litigation and indemnification costs and any damages ultimately borne by us as a result of these lawsuits and investigations could have a material adverse effect on our business, financial condition, results of operations or cash flows.

An adverse outcome with respect to investigations of aaiPharma that are being conducted by the SEC and the U.S. Attorney's Office could have a material adverse effect on our results of operations and liquidity.

On August 7, 2003 we received a letter from the staff of the Enforcement Division requesting voluntary production of certain documents. We responded to this letter on August 21, 2003 and supplemented our response on August 29, 2003.

Independent of the August 7, 2003 inquiry letter, on September 26, 2003, certain members of our board and management voluntarily met with, and provided documents to, the staff of the Enforcement Division. As a follow-up to this September 26, 2003 meeting and as part of the inquiry initiated on August 7, 2003, on October 8, 2003, we received a further request from staff of the Enforcement Division for voluntary production of certain documents, to which we responded on October 30, 2003.

On January 14, 2004 and April 26, 2004, we received letters from the SEC's Division of Corporate Finance commenting on, asking questions about, and seeking additional disclosure with respect to certain of our periodic reports. We have responded to these letters.

In April 2004, in connection with an investigation conducted by the U.S. Attorneys Office, we received five federal grand jury subpoenas for document production and potential testimony related to, among other things, certain transactions regarding our 2002 and 2003 financial information, the terms, conditions of employment and compensation arrangements of certain of our senior management personnel, compensation and incentive arrangements for employees responsible for the sale of our Brethine, Darvocet, calcitriol, azathioprine and Darvon Compound products, quantities of the foregoing products in distribution channels, financial benefits with respect to specified corporate transactions to our senior management and others, certain loans obtained by us, extensions of credit, if any, by us to officers or directors, accounting for sales and returns of our foregoing products, our analysts' conference calls on financial results, internal and external investigations of pharmaceutical product sales activities, and related matters. We have also been advised that the SEC has initiated an inquiry into at least the same issues investigated by the Special Committee. The U.S. Attorneys Office has advised that we may also receive a subpoena from the SEC.

We and the Special Committee have agreed to cooperate fully with the government investigations, and the Special Committee has agreed to share all results of its investigation with the SEC and the U.S. Attorneys Office. To that end, two meetings of our outside counsel with attorneys for the U.S. Attorneys Office and

the SEC have taken place and numerous documents as requested by these government agencies have been voluntarily produced. We are working to schedule a third meeting with the U.S. Attorneys Office and the SEC in July in order to provide additional information related to the Special Committee's investigation to these government agencies. We and the Special Committee intend to facilitate any interviews of our employees or officers that may be requested by these government agencies.

The Department of Justice, SEC and other government agencies that are investigating or might commence an investigation of aaiPharma could impose, based on a claim of fraud, material misstatements, violation of false claims law or otherwise, civil and/or criminal sanctions, including fines, penalties, and/or administrative remedies. If any government sanctions are imposed, which we cannot predict or reasonably estimate at this time, our business, financial condition, results of operations or cash flows could be materially adversely affected. These matters have resulted, and are expected to continue to result, in a significant diversion of management's attention and resources and in significant professional fees.

In addition, there may be additional governmental investigations pending of which we are not yet aware.

We have certain obligations to indemnify our officers and directors, and we may not have sufficient insurance coverage available for this purpose. We may be forced to pay these indemnification costs directly, and we may not be able to maintain existing levels of coverage, which could make it difficult to attract or retain qualified directors and officers.

Our bylaws require that we indemnify our directors and officers under specified circumstances. Although we have purchased D&O liability insurance for our directors and officers to fund a portion of these obligations, if our insurance carriers should deny coverage, or if the indemnification costs exceed the insurance coverage, we may be forced to bear some or all of these indemnification costs directly, which could be substantial and may have an adverse effect on our business, financial condition, results of operations and cash flows. If the cost of this insurance increases significantly, or if this insurance becomes unavailable, we may not be able to maintain or increase our levels of insurance coverage for our directors and officers, which could make it difficult to attract or retain qualified directors and officers.

As a result of our announcement regarding unusual sales of certain products and the initiation of an inquiry by the Special Committee, and the increased scrutiny of financial disclosure generally, investor confidence and the confidence of our lenders in us has suffered and could suffer further. The results of our investigations and any subsequent adjustments to our financial statements could have such effect and further materially and adversely affect the trading price of our securities and our ability to access the capital markets and increase our litigation risks.

As a result of our announcement regarding unusual sales of certain products and the appointment of the Special Committee to investigate such sales, and the increased scrutiny of our financial disclosures generally, investor confidence and the confidence of our lenders in us has suffered and could suffer further. The U.S. Attorney's Office and the SEC are scrutinizing our financial reporting practices with respect to such unusual sales. The results of the Special Committee's investigation and the material modifications to our 2002 and 2003 financial results as included in this Annual Report on Form 10-K may further adversely affect confidence in us and further materially and adversely affect the trading price of our securities and our ability to access capital markets and increases our litigation risks. The institution of further litigation and government investigations could also have a material adverse impact on us.

The circumstances surrounding our Special Committee investigation, pending litigation and governmental investigations and adjustments to our financial statements could make it difficult for us to hire and retain key personnel.

The investigation by our Special Committee, investigations by the SEC and/or the U.S. Attorney's Office and pending securities and ERISA class actions and other litigation, and recent announced changes to our

management team, have created substantial uncertainty regarding our ability to focus on our business operations and remain competitive with other companies in our industry. Because of this uncertainty, we may have difficulty motivating and retaining key personnel or replacing key personnel who leave aaiPharma. In addition, due to the recent substantial declines in the price of our common stock, the exercise price of outstanding employee stock options substantially exceeds the trading price of our common stock. The loss in value of these stock options may affect our ability to retain our key employees, which could seriously harm our ability to generate revenue, manage day-to-day operations, and deliver our products and services.

Risks Related to Our Business

Our internal controls have been inadequate and could adversely affect our financial condition and ability to carry out our business plan.

We have determined that unusual, significant sales of our Brethine injectable and Darvocet N-100 products occurred during the second half of 2003, and that certain wholesalers were given a right to return quantities of new products that we launched in 2003 to the extent that they had not sold the new products within a specified time. We have also become aware of opportunities for an employee or group of employees to take actions to circumvent our internal controls. Thus, we are undertaking a thorough review of our internal control structure with the assistance of our independent auditors who have identified material weaknesses in and a reportable condition with respect to our internal controls. In addition, we may have to commit substantial resources, including time from our management team, to improve our internal controls which may negatively affect our ability to implement our business plan. Further, a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no system of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. A failure of our controls and procedures to detect error or fraud could seriously harm our business and results of operations.

We may have overpaid for our branded product lines that may not produce sufficient cash flow to repay indebtedness incurred in connection with the acquisition or to provide an acceptable rate of return on our investment.

We have increased our net revenues through a series of acquisitions of branded products. The acquisition prices that we paid were based upon many factors, including our analysis of sales history, forecasted sales, competition, and our judgment with respect to marketing potential, brand strength and product improvement opportunities. The revenues we derive from any of these product lines may be lower than amounts we expected when we acquired these product lines. We funded our acquisitions of M.V.I., Brethine, Darvon, Darvocet, Oramorph SR, Roxanol, and Roxicodone by borrowings under predecessor senior credit facilities, and the net proceeds from our sale of the senior subordinated notes. We may have overpaid for our branded product lines that may not produce sufficient cash flow to repay indebtedness incurred in connection with the acquisition or to provide an acceptable rate of return on our investment.

Our branded products are subject to generic competition and increased generic substitution for our branded products may result in a decrease in our revenues and materially affect our liquidity.

Our branded products are subject to generic competition. In 2004, the Food and Drug Administration approved generic versions of our Roxicodone and Brethine injectable products. There is no proprietary protection for most of the branded pharmaceutical products that we sell, and as a result our branded pharmaceutical products are or may become subject to competition from generic substitutes. In May 2004, a generic version of injectable Brethine was introduced. If our competitors can supply significant amounts

of the generic product to the market, our revenues from sales of Brethine injectable product may be substantially reduced. In addition, given levels of inventory of this product in the distribution channel, our cash flows from sales of this product may be negatively affected and we may experience significant returns of this product which could materially adversely affect our liquidity. Generic substitutes for our branded products, which may be precisely identical to our branded products, are sold by competitors at significantly lower prices. If consumers and physicians do not believe that our branded products have greater benefits than their generic equivalents, they may elect generic equivalents or other substitute products in lieu of our branded products, which may result in decreased revenues for our branded products. In addition, any further increase in the amount of generic and other competition against any one or more of our products could further lower prices and unit sales. In addition, pressures to reduce pharmaceutical costs, including from third-party payers such as health maintenance organizations, or HMOs, and health insurers, may result in physicians or pharmacies increasingly using generic substitutes. State and federal legislation, and decisions by state and federal government agencies with the power to determine or influence purchasing decisions on products sold to government agencies or through government funded programs, may be enacted or made that would adversely affect purchases of branded pharmaceutical products. Such legislation or government agency decisions may more broadly mandate substitution of generic products for prescriptions written for branded products, establish preferred or exclusionary product lists that favor generic products, or otherwise establish or influence product purchases. Competition from generic products or additional legislation or regulatory developments favoring generic products, creating preferred or exclusionary product lists, or establishing or influencing purchasing decisions could cause our sales of branded products to decrease and could have a material adverse effect on our business, financial condition, and results of operations.

A small number of customers account for a large portion of our sales and the loss of one of them, or changes in their purchasing or payment patterns or inventories, could result in reduced sales or adversely impact our financial performance.

We are heavily dependent on sales of our products to three large national wholesalers, McKesson Corporation, Cardinal Health Inc., and AmerisourceBergen Corporation, which then resell our products out of their inventories to pharmacies and other indirect customers for use in meeting ultimate prescription demand. Our results of operations, including, in particular, product sales revenue, may vary from quarter to quarter due to buying and payment patterns and inventories of our wholesalers. In the event wholesalers with whom we do business determine to limit their purchases of our inventory or withhold payments from us, sales of our products or our cash flows could be materially adversely affected. For example, in advance of an anticipated price increase, many of our customers may order pharmaceutical products in larger than normal quantities. The ordering of excess quantities in any quarter could cause sales of some of our branded pharmaceutical products to be lower in subsequent quarters than they would have been otherwise. We believe that excess sales of our Brethine injectable and Darvocet N-100 products during the second half of 2003 will significantly reduce our sales of these products in 2004. The small number of wholesale drug distributors, consolidation in this industry or financial difficulties of these distributors could result in the combination or elimination of warehouses, which could temporarily increase returns of our products or, as a result of distributors reducing inventory levels, delay the purchase of our products.

We do not anticipate receiving further material payments in connection with our significant development agreement in the future, and we may be unable to replace this revenue stream.

We have a significant development agreement under which we received product development revenues of \$13.0 million in 2003, \$16.9 million in 2002 and \$14.9 million in 2001 and development services revenues of \$2.7 million in 2003, \$4.7 million in 2002 and \$6.3 million in 2001. During this time period, we recorded research and development expenses of \$1.0 million in 2003, \$0.7 million in 2002 and \$2.3 million in 2001 related to this agreement. In April 2004, we entered into an agreement to receive a prepayment of amounts that would otherwise be paid to us quarterly through the second quarter of 2005 under this significant development agreement. These payments would have aggregated \$15.4 million, and in April

2004 we received approximately \$15.0 million in gross proceeds from the prepayment. We do not anticipate that we will receive further material payments in connection with this significant development agreement in the future. If we are unable to replace this revenue stream, our results of operations and cash flows may be materially adversely affected.

We are dependent on third parties for the manufacture of our products, for critical raw materials and services.

We are dependent on third parties for certain essential business functions, and problems with these third-party arrangements could materially adversely affect our ability to manufacture and sell products and our business, financial condition, and results of operations.

We are dependent on third parties for the manufacture of most of our proprietary products. Our manufacturing dependence upon third parties may adversely affect our profit margins and our ability to deliver our products on a timely and competitive basis. If we are unable to retain or replace third-party manufacturers on commercially acceptable terms, we may not be able to distribute our products as planned. If we encounter delays or difficulties with contract manufacturers in producing or packaging our products, the distribution, marketing and subsequent sales of these products would be adversely affected, and we may have to seek alternative sources of supply, lose sales or abandon or divest a product line on unsatisfactory terms. We may be unable to enter into alternative supply arrangements at commercially acceptable rates on a timely basis, if at all. The manufacturers that we utilize may not be able to provide us with sufficient quantities of our products, and the products supplied to us may not meet our specifications. Moreover, failure of our contract manufacturers to follow good manufacturing practices as mandated by the FDA, could suspend or halt manufacturing at these sites. Additionally, modifications, enhancements, or changes in manufacturing sites of approved products are subject to FDA approval that we may or may not be able to obtain and that may be subject to a lengthy application process.

After expiration of our existing third-party supply contracts, our manufacturing costs for those products supplied under these contracts could be higher and any transfer of manufacturing of these products, including any transfer to our own or new third-party manufacturing facilities, may cause us to incur significant manufacturing start-up costs. Our third-party supply contracts are scheduled to expire beginning over the next few years, and we may be unable to renew agreements with our current suppliers since in a number of cases our suppliers are companies from whom we acquired our branded products and the supply agreements were entered into in connection with the purchase of the branded product line. Additionally, any change of the manufacturing site of any of these products would require FDA approval of the new manufacturing facility. FDA approval, however, is not within our control, and we may not receive the necessary approval within our anticipated time schedule, if at all.

We are also dependent on third parties for the supply of critical raw materials and packaging supplies. Sales of our products will be dependent on our ability to obtain FDA-approved supplies of raw materials, including active and inactive pharmaceutical ingredients, and packaging materials, at commercially acceptable prices and terms, in time to satisfy critical product development, testing, analytical and manufacturing activities, customer contracts, or our development plans. The FDA must approve the supply source of many ingredients for our products. The qualification of a new supply source could delay the manufacture of the drug involved. Arrangements with our foreign suppliers are subject to certain additional risks, including the availability of governmental clearances, export duties, political instability, currency fluctuations, and restrictions on the transfer of funds. Any constraints on the supply of raw materials could materially and adversely affect our business, financial condition, and results of operations.

We use, and are dependent on, a contract distribution program for warehousing of our branded products. We have contracted with a national pharmaceutical product distribution company to provide warehousing, product distribution, inventory tracking, customer service and financial administrative assistance related to our product distribution program. We are dependent on the capabilities of this third party to distribute our

products effectively. We do not have extensive experience performing these functions ourselves and may suffer significant disruption if in the future we have to perform these functions or find alternative providers.

Our new products and line extensions, including Darvocet A500 may not produce revenues sufficient to justify the cost of acquiring or developing these products or our related direct costs and selling expense.

Our business plan for our Darvocet line extensions, including Darvocet A500, was based on the belief that these products would not be subject to immediate competition from generic products, although they would be subject to potential generic competition. In some jurisdictions, however, pharmacists may fill prescriptions written for Darvocet A500 and similar Darvocet line extension products with generic products that, though not recognized by the FDA as therapeutically equivalent to the Darvocet products, may be deemed by the pharmacist to be therapeutically equivalent to those products. It is our understanding that a pharmacist's profit margin on these generic products generally exceeds the pharmacist's profit margin on our branded Darvocet line extension products. These factors may result in lower revenues from these Darvocet line extensions than we had internally estimated. We have written off the full amount of the Darvocet A-500 assets we acquired in July 2003 because we do not anticipate additional material income from this product. Our new products and line extensions may not produce revenues sufficient to justify our cost of acquiring or developing these products or our direct costs and selling expense.

If we cannot sell our Darvocet A500 and other products in amounts greater than our minimum purchase requirements under our supply agreement, our results of operations and cash flows may be adversely affected.

Our original supply agreement for Darvocet A500 requires us to purchase certain minimum levels of this product over the initial three-year period of this agreement, subject to specified terms and conditions. We amended the agreement to allow other products manufactured by the third party on our behalf to count towards this minimum requirement, but have not yet agreed upon the terms for manufacturing these additional products, including price. If sales of our products do not significantly increase from current rates or we are unable to transfer the manufacturing of additional products to the third party in a timely manner, we may incur losses in connection with the purchase commitments under the supply agreement. In the event we incur losses in connection with the purchase commitments under the supply agreements, there may be a material adverse effect upon our results of operations and cash flows.

Because we have a limited number of product lines, a material adverse change in any one of our product lines could materially adversely affect our results of operations and cash flows.

Our success is largely dependent upon a limited number of key product lines, which means that any unfavorable developments with respect to any one product line could materially adversely affect us. Sales of our branded product lines, particularly Darvon, Darvocet, and Brethine, represent a significant portion of our total revenues. The divestiture of our M.V.I. business reduced the number of key product lines that we sell. Accordingly, any factor adversely affecting sales of any of these products, such as the recent introduction of generic competitors of our injectable Brethine and Roxicodone products, could have a material adverse effect on our business, financial condition, and results of operations. In addition, any perceived problems with these products, such as any problem with their safety or efficacy, could have a similar material adverse effect.

We may incur substantial expense to develop products that we never successfully commercialize.

We incur substantial research and development expenses, and other expenses, attempting to develop new or improved products or product line extensions. The products or line extensions to which we devote operational and financial resources could be commercial failures. Successful commercialization of products and product line extensions requires accurate anticipation of market and customer acceptance of particular products, customers' needs, the sale of competitive products, and emerging technological trends, among

other things. Additionally, for successful product development, we must complete many complex formulation and analytical testing requirements and obtain regulatory approvals from the FDA and other regulatory agencies. When developed, new or reformulated drugs may not exhibit desired characteristics or may not be accepted by the marketplace. Complications can also arise during production scale-up. Our products and line extensions may encounter unexpected, unresolvable patent conflicts, or may not have enforceable intellectual property rights. Delays or problems also may arise from internal conflicts for resource availability, personnel errors or equipment failures. If we incur significant expenses for a product or line extension that we do not successfully develop and commercialize, there could be a material adverse effect on our business, financial condition and results of operations.

Introductions by us of line extensions of our existing products may require that we make unexpected changes in our estimates for future product returns and reserves for obsolete inventory which would adversely affect our operating results.

Part of our business strategy includes the introduction of line extensions of our existing products to create marketing advantages and extend the life cycles of our product lines. From time to time, we may seek to introduce line extensions on an expedited basis, even though there are significant levels of inventories of product which may be rendered obsolete or otherwise adversely affected by the line extension. This may require us to increase our estimate for returns of product on hand at wholesalers, which are recorded as a reduction of our net revenues, and increase our reserve for our inventory which is recorded as a direct cost. Accordingly, the introduction of line extensions may adversely affect our operating results.

There is a risk that we may incur additional charges for intangible asset impairment.

When we acquire the rights to manufacture and sell a product, we record the aggregate purchase price, along with the value of the product related liabilities we assume, as intangible assets. We use the assistance of valuation consultants to help us allocate the purchase price to the fair value of the various intangible assets we have acquired. Then, we must determine if the asset has an indefinite life or a definite life and estimate the economic useful life of each of the definite-lived intangible assets in order to amortize their cost as an expense in our statement of operations over the estimated economic useful life of the related asset. The factors that drive the actual economic useful life of a pharmaceutical product are inherently uncertain, and include physician loyalty and prescribing patterns, competition by products prescribed for similar indications, future introductions of competing products not yet FDA approved, the impact of promotional efforts and many other issues. We use all of these factors in initially estimating the economic useful lives of our products, and we also continuously monitor these factors for indications of appropriate revisions.

In assessing the recoverability of our intangible assets, we must make assumptions regarding estimated undiscounted future cash flows and other factors. If the estimated undiscounted future cash flows do not exceed the carrying value of the intangible assets we must determine the fair value of the intangible assets. If the fair value of the intangible assets is less than its carrying value, an impairment loss will be recognized in an amount equal to the difference. If these estimates or their related assumptions change in the future, we may be required to record impairment changes for these assets. In addition, material adjustments to our forecasted revenues from the sales of any of our acquired product lines including Brethine and Darvocet may require us to employ different assumptions with respect to our estimated cash flows. We review intangible assets for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If we determine that an intangible asset is impaired, a non-cash impairment charge would be recognized.

As circumstances after an acquisition can change, the value of intangible assets may not be realized by us. If we determine that impairment has occurred, we would be required to write-off the impaired portion of the unamortized intangible assets, which could have a material adverse effect on our results of operations in the period in which the write-off occurs. In addition, in the event of a sale of any of our assets, we cannot be certain that our recorded value of such intangible assets would be recovered.

We may be unable to secure or enforce adequate intellectual property rights to protect the new products or technologies we develop, and our existing intellectual property rights may not be adequate to protect us or provide us with a competitive advantage.

Our ability to successfully commercialize new products or technologies is dependent upon our ability to secure and enforce strong intellectual property rights, generally patents, and we may be unable to do so. To obtain patent protection, we must be able to successfully persuade the U.S. Patent and Trademark Office and its foreign counterparts to issue patents on a timely basis and possibly in the face of third-party challenges. Even if we are granted a patent, our rights may later be challenged or circumvented by third parties. The issuance of a patent is not conclusive as to its validity or enforceability. Litigation to enforce our patents generally will involve substantial professional fees and costs and may ultimately prove to be unsuccessful. In addition, we may receive notices from third parties regarding patent claims against us or our subsidiaries. Any such claims, with or without merit, could be time-consuming to defend, result in costly litigation, divert our management's attention and resources, and cause us to incur significant expenses or, in the event of adverse decisions, significant damages owed to the patent owner. In addition, any potential intellectual property litigation could require that we stop selling our products, obtain a license from the owner to sell or use the relevant intellectual property, which we may not be able to obtain on favorable terms, if at all, or modify our products to avoid using the relevant intellectual property. In the event of a successful claim of infringement against us, our business, financial condition and results of operations could be materially and adversely affected.

Additionally, we also rely on trade secrets and other unprotected proprietary knowledge, which we generally seek to protect by confidentiality, non-disclosure and assignment of invention agreements with our employees, consultants, licensees and other companies. These agreements, however, may be breached or may not be enforceable, or we may not have adequate remedies for a breach by the other party. Additionally, our trade secrets may become known by our competitors. Parties to those agreements may claim rights to intellectual property arising out of their work. The disclosure or misappropriation of our intellectual property for any of these reasons could materially and adversely affect our business, financial condition or results of operations.

We may be unable to obtain government approval for our products or comply with government regulations relating to our business.

The commercialization of pharmaceutical products is subject to extensive federal, state and local regulation in the United States and similar foreign regulation. We do not know the extent to which we may be affected by legislative and other regulatory actions and developments concerning various aspects of our operations, our products and the health care field generally. We do not know what effect changes in governmental regulation and other actions or decisions by governmental agencies may have on our business in the future. Any changes could require changes to manufacturing methods or facilities, pharmaceutical importation, expanded or different labeling, new approvals, the recall, replacement or discontinuance of certain products, additional record keeping, price or purchase controls or limitations, and expanded documentation of the properties of certain products and scientific substantiation. Any regulatory changes could have a material adverse effect on our business, financial condition and results of operations or our competitive position. The manufacturing, processing, formulation, packaging, labeling, distribution, importation, pricing, reimbursement and advertising of our products, and disposal of waste products arising from these activities, are also subject to regulation by the U.S. Drug Enforcement Administration, the Federal Trade Commission, the U.S. Consumer Product Safety Commission, the U.S. Department of Agriculture, the Occupational Safety and Health Administration, the U.S. Environmental Protection Agency, the U.S. Customs Service and the Centers for Medicare and Medicaid Services, as well as state, local and foreign governments.

We will be required to obtain approval from the FDA based upon pre-clinical testing, clinical trials showing safety and effectiveness, chemistry and manufacturing control data, and other data and information before marketing most drug products. The generation of the required data is regulated by the FDA and can be time-consuming and expensive, and the results might not justify approval. Our FDA product filings may not be approved in a timely manner, if at all, and we may be unable to meet other regulatory requirements for our products. Pharmaceutical products also must be distributed, sampled, advertised and promoted in accordance with FDA requirements. Even if we are successful in obtaining all required pre-marketing approvals, post-marketing requirements and any failure on our part to comply with other regulations could result in suspension or limitation of approvals or commercial activities pertaining to affected products. The FDA could also require reformulation of products during the post-marketing stage.

All of our drugs must be manufactured in conformity with current Good Manufacturing Practice regulations, as interpreted and enforced by the FDA, and drug products subject to an FDA-approved application must be manufactured, processed, packaged, held and labeled in accordance with information contained in the application. Additionally, modifications, enhancements or changes in manufacturing sites of approved products are, in many circumstances, subject to FDA approval, which may be subject to a lengthy application process or which we may be unable to obtain. Our facilities, including the facilities used in our development services business, and those of our third-party manufacturers, are periodically subject to inspection by the FDA and other governmental agencies, and operations at these facilities could be interrupted or halted if such inspections are unsatisfactory.

Failure to comply with FDA or other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production or distribution, suspension of the FDA's review of our product applications, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have instituted internal compliance programs, if compliance is deficient in any significant way, it could have a material adverse effect on us. Most of our suppliers are subject to similar regulations and periodic inspections.

The federal health care program antikickback statute makes it illegal for anyone to knowingly and willfully make or receive "kickbacks" in return for any health care item or service reimbursed under any federally financed healthcare program. This statute applies to arrangements between pharmaceutical companies and the persons to whom they market, promote, sell and distribute their products. Federal false claims laws prohibit any person from knowingly making a false claim to the federal government for payment. Recently, several pharmaceutical companies have been prosecuted under these laws, even though they did not submit claims to government healthcare programs. The prosecutors alleged that they were inflating drug prices they report to pricing services, which are in turn used by the government to set Medicare and Medicaid reimbursement rates. Pharmaceutical companies also have been prosecuted under these laws for allegedly providing free products to customers with the expectation that the customers would bill federal programs for the products. Additionally, the majority of states have laws similar to the federal antikickback law and false claims laws. Sanctions under these federal and state laws include monetary penalties, exclusion from reimbursement for products under government programs, criminal fines and imprisonment. While we have internal policies and practices requiring compliance with the health care fraud and abuse laws and false claims laws, it is possible that some business practices could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

On January 2, 2004, we received separate letters from the Kentucky Office of Attorney General and the Florida Office of Attorney General advising that each was currently investigating allegations regarding our pricing practices related to our average manufacturer price and best price calculations that are used by the

government to set Medicaid reimbursement rates. Neither letter requested that we provide any information, and each letter merely requested that we retain all documents with respect to these calculations pursuant to a newly adopted federal regulation that would have permitted the destruction of these documents three years after the applicable prices were reported, except to the extent we were aware of an ongoing investigation. It is our understanding that many other pharmaceutical companies received similar letters at that time from attorneys general in a number of states and that such letters may have been in response to the new federal regulation that would have otherwise allowed the destruction of documents reflecting these pricing calculations. A number of attorneys general, including the Florida and Kentucky attorneys general, petitioned the U.S. Secretary of Health and Human Services to withdraw the new regulation. We are not aware of any further developments in these investigations.

Additionally, our business involves the controlled storage, use and disposal of hazardous or highly potent materials. We are subject to numerous environmental laws and regulations in the jurisdictions in which we operate. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply in all material respects with the standards prescribed by law and regulation in each of our locations, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable to governmental authorities or private parties for any damages that result, and the liability could exceed our resources. In addition, we could be held liable for costs associated with contamination of properties currently or formerly occupied by us, or at other parties' disposal sites where we dispose or have disposed of hazardous wastes, even though this contamination may have been caused by third parties or the disposal may have complied with the regulatory requirements then in place. Current or future environmental laws and regulations, or adverse changes in the way current laws and regulations are interpreted or enforced, may materially adversely affect our business, financial condition and results of operations. We maintain liability insurance for some environmental risks that our management believes to be appropriate and in accordance with industry practice. However, we may incur liabilities beyond the limits or outside the coverage of our insurance and may not be able to maintain insurance on acceptable terms.

In connection with our activities outside the U.S., we are subject to foreign regulatory requirements governing the testing, approval, manufacture, labeling, marketing and sale of pharmaceutical products. These requirements vary from country to country. Even if FDA approval has been obtained for a product, approval by comparable regulatory authorities of foreign countries must be obtained prior to marketing the product in those countries. For example, some of our foreign operations are subject to regulations by the European Medicines Evaluations Agency and the U.K. Medicines Control Agency. The approval process may be more or less rigorous from country to country, and the time required for approval may be longer or shorter than that required in the U.S. Clinical studies conducted outside of any particular country may not be accepted by that country, and the approval of a pharmaceutical product in one country does not assure that the product will be approved in another country. In addition, regulatory agency approval of pricing is required in many countries and may be required for our marketing of any drug in those countries.

Product liability claims or product recalls could harm our business, financial condition and results of operations.

We face an inherent business risk of exposure to product liability claims in the event that the use of our products or products that we manufacture for others is alleged to have resulted in adverse effects. Such risks will exist even with respect to those products that receive regulatory approval for commercial sale. While we will take what we believe are appropriate precautions, we may not be able to avoid significant product liability exposure. Although we maintain product liability insurance, this insurance may not be sufficient to cover all potential claims against us or involving our products or products manufactured for others. Also, adequate insurance coverage may not be available in the future at acceptable costs, if at all. When we acquire or develop new products, we cannot assure that additional liability insurance coverage for

these new products will be available on acceptable terms, if at all. The assertion of this type of claim could have a material adverse affect on our business, financial condition and results of operations. Product recalls may be issued at our discretion or at the discretion of government agencies or others having regulatory authority for pharmaceutical product sales. Recalls could have a material adverse effect on our business, financial condition and results of operations.

We are vulnerable to pressures from third-party payers.

Our commercial success in product sales will depend on patients being reimbursed by third-party health care payers, such as government and private health insurers and managed care organizations. Third-party payers are increasingly challenging the pricing of medical products and services. For example, third-party payers strenuously discourage use of branded products when generic substitutes are available, although they may prefer established branded products over more expensive newer products for the same indication. As a result, reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product acquisition and development. If adequate reimbursement levels are not provided, our business, financial condition and results of operations could be materially and adversely affected.

The market for our products may also be limited by other actions of third-party payers. For example, many managed health care organizations are now limiting the pharmaceutical products that are on their lists of approved drugs. The resulting competition among pharmaceutical companies to place their products on these formulary lists has created a trend of downward pricing pressure in the industry. In addition, many managed care organizations are pursuing various ways to reduce pharmaceutical costs and are considering formulary contracts primarily with those pharmaceutical companies that can offer a broad line of products for a given class of therapy or disease, which we cannot do. Our products may not be included on the approved drug list of managed care organizations, and downward pricing pressures in the industry generally could materially and adversely impact our business, financial condition and results of operations.

New legislation or regulatory proposals may adversely affect our revenues.

A number of legislative proposals aimed at reducing the costs of medical products and services have been enacted or proposed. For example, certain state governments have enacted legislation that seeks to reduce the price paid by the Medicaid program for prescription drugs. In Florida and Michigan, pharmaceutical companies that sell drugs reimbursed under state Medicaid programs are now required to offer rebates in addition to the existing rebates mandated by Federal law in order for their prescription drugs to be placed on the state's preferred list of drugs eligible for Medicaid reimbursement. A number of states are considering additional legislation and other measures that would, if enacted, further adversely affect revenues from the sale of branded drugs, for example, through limits on the purchase of branded drugs by state institutions and restrictions on reimbursement for branded drugs in programs subject to state jurisdiction.

In addition, in 2000, Congress directed the FDA to adopt regulations allowing the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs were sold at a lower price. Although the Secretary of Health and Human Services has refused to implement this directive, in July 2003 the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we receive for our products. For most of our branded products, we own only the U.S. distribution rights, while others own the rights to distribute these products outside the United States. Accordingly, sales of our products in the United States could be adversely affected by the importation of equivalent products that are manufactured by others and are available outside the United States.

Changes in the Medicare, Medicaid or similar governmental programs or the amounts paid by those programs for our services may adversely affect our earnings. These programs are highly regulated and subject to frequent and substantial changes and cost containment measures. In recent years, changes in these programs have limited and reduced reimbursement to providers. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, creates a new, voluntary prescription drug benefit under the Social Security Act, which we refer to as "Medicare Drug Benefit." Beginning in 2006, Medicare beneficiaries entitled to Part A or enrolled in Part B, as well as certain other Medicare enrollees, will be eligible for the Medicare Drug Benefit. Regulations implementing the Medicare Drug Benefit have not yet been published, and the Medicare Drug Act requires that the Federal Trade Commission conduct a study and make recommendations regarding additional legislation that may be needed concerning the Medicare Drug Benefit. We are unable at this time to predict or estimate the financial impact of this new legislation. Additionally, several large pharmaceutical companies have recently adopted discount plans for the elderly. Our business, financial condition and results of operations could be materially and adversely affected if recently established or future legislative or regulatory programs that are designed to reduce the costs of medical products and services are effective or require consumers to use generic substitutes or other alternatives for our branded products.

Our stock price is volatile, which could result in substantial losses for investors purchasing shares.

Our operating results may fluctuate from quarter to quarter and from year to year, causing our stock price to fluctuate. The market price of our common stock will be affected by our ability to meet analysts' and investors' expectations. Failure to meet these expectations, even slightly, could cause the market price of our common stock to fall significantly. The market prices for securities of drug delivery, biotechnology and pharmaceutical companies historically, and our stock in particular, have been highly volatile and may be highly volatile in the future. Other factors that could materially adversely affect our stock price include:

- demand by consumers for our products and the products we produce for others;
- the prices that we can obtain for such products;
- the level of product and price competition;
- competitive new product introductions, including generic competition;
- distributors' and wholesalers' ordering patterns;
- levels of our products in the distribution channels;
- the outcome and costs of litigation brought by and against us;
- timely success in product development and regulatory approvals for new products and line extensions;
- actions by the FDA in connection with submissions related to our products or those of our competitors;
- other governmental regulations and actions affecting our products or those of our competitors;
- third-party payer decisions and actions affecting our products or those of our competitors;
- developments in patent or other proprietary rights owned by us or others;
- our manufacturing efficiency and capacity and the ability of our product and raw material suppliers to supply us with conforming products and materials on a timely and regulatory compliant basis;
- our ability to control costs;
- fluctuations in our operating results;
- the number and profitability of new services agreements that we enter into;
- the number and timing of product development milestones that we achieve under third-party agreements and other contracts with customers;
- the level of spending on research and development by us and by the pharmaceutical industry as a whole;

- announcements of technological collaborations, innovations or new products by us or our competitors;
- public concern as to the safety of our products or the products we manufacture for others;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- decisions by our pharmaceutical company partners relating to the products incorporating our technologies; and
- general economic and market conditions.

Our business is subject to changing regulation of corporate governance and public disclosure that has increased both our costs and the risk of noncompliance.

Because our common stock is publicly traded, we are subject to certain rules and regulations of federal, state and financial market exchange entities charged with the protection of investors and the oversight of companies whose securities are publicly traded. These entities, including the Public Company Accounting Oversight Board, the SEC and NASDAQ, have recently issued new requirements and regulations and continue developing additional regulations and requirements in response to recent corporate scandals and laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002. Our efforts to comply with these new regulations have resulted in, and are likely to continue resulting in, increased general and administrative expenses and diversion of management time and attention from revenue-generating activities to compliance activities.

In particular, our efforts to prepare to comply with Section 404 of the Sarbanes-Oxley Act and related regulations regarding our management's required assessment of our internal control over financial reporting and our independent auditors' attestation of that assessment has required, and continues to require, the commitment of significant financial and managerial resources. In part to prepare for compliance with Section 404, as well as to generally improve our internal control environment, we have undertaken substantial measures, including, among other things, costly projects to centralize both our accounting and information technology systems. These projects, which represent both operational and compliance risks, require significant resources and must be completed in a timely manner in order to enable us to comply with the Section 404 requirements. Although management believes that ongoing efforts to improve our internal control over financial reporting will enable management to provide the required report, and our independent auditors to provide the required attestation, under Section 404 as of December 31, 2004, we can give no assurance that such efforts will be completed on a timely and successful basis to enable our management and independent auditors to provide the required report and attestation.

Moreover, because the new and changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices.

Cautionary Statement Regarding Forward-Looking Statements

This document contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Words such as "estimate," "project," "intend," "anticipate," "believe" and similar expressions are intended to identify forward-looking statements. The forward-looking statements contained in this document include statements about future financial and operating results, including the anticipated financial condition, results of operations, business strategies, operating efficiencies, competitive positions, growth opportunities for existing products, plans and objectives of management and markets for our common stock. These statements are based on the current expectations and beliefs of our management and are subject to a number of factors and uncertainties,

including the matters noted above, that could cause actual results to differ materially from those described in the forward-looking statements. These statements are not guarantees of future performance, involve certain risks, uncertainties and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed in the forward-looking statement. In any forward-looking statement in which we express an expectation or belief as to future results, that expectation or belief is expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will result or be achieved or accomplished. Additional risks and uncertainties pertaining to the following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements:

- demand by consumers for our products and the products we produces for others;
- the prices that we can obtain for such products;
- the level of product and price competition;
- competitive new product introductions, including generic competition;
- distributors' and wholesalers' ordering patterns;
- levels of our products in the distribution channels;
- the outcome and costs of governmental investigation;
- the outcome and costs of litigation brought by and against us;
- timely success in product development and regulatory approvals for new products and line extensions;
- actions by the FDA in connection with submissions related to our products or those of our competitors;
- other governmental regulations and actions affecting our products or those of our competitors;
- third-party payer decisions and actions affecting our products or those of our competitors;
- developments in patent or other proprietary rights owned by us or others; and
- the other factors discussed in "- Risks Factors and Forward-Looking Statements."

We do not undertake any obligation to (and expressly disclaim any obligation to) update or alter our forward-looking statements, whether as a result of new information, future events or otherwise.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As a result of global operating activities, we are exposed to risks associated with changes in foreign exchange rates. As foreign exchange rates change, the U. S. dollar equivalent of revenues and expenses denominated in foreign currencies change and can have an adverse impact on our operating results. To seek to minimize our risk from foreign exchange movement, we may use local debt to fund our foreign operations. If foreign exchange rates were to increase by 10%, our operating results would have been lower by \$100,000 in 2003 due to the reduction in reported results from European operations.

We are also exposed to fluctuations in interest rates on variable rate debt instruments tied to LIBOR, as discussed in "Management's Discussion and Analysis of Financial Condition – Liquidity and Capital Resources." If interest rates were to increase by 1%, annual interest expense on variable rate debt tied to interest rates would increase by approximately \$1.0 million.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

**Board of Directors and Stockholders
aaiPharma Inc.**

We have audited the accompanying consolidated balance sheets of aaiPharma Inc. and subsidiaries as of December 31, 2003 and 2002, and the related consolidated statements of operations, cash flows, stockholders' equity, and comprehensive income (loss) for each of the three years in the period ended December 31, 2003. Our audits also included the financial statement schedule listed in the index at Item 15(d). These financial statements and schedule 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 aaiPharma Inc. and subsidiaries at December 31, 2003 and 2002, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2003, 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.

/s/ Ernst & Young LLP
Raleigh, North Carolina
May 14, 2004

aaiPharma Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Years Ended December 31,		
	2003	2002 (as restated)	2001
Net revenues:			
Product sales	\$ 122,021	\$ 128,462	\$ 27,448
Product development	16,468	19,610	20,426
Development services (includes related party net revenues of \$630, \$1,556 and \$323)	86,488	82,438	93,199
	<u>224,977</u>	<u>230,510</u>	<u>141,073</u>
Operating costs and expenses:			
Direct costs (excluding depreciation and royalty expense):			
Product sales (includes acquired product rights amortization of \$12,273, \$9,239, and \$0)	62,970	41,884	13,337
Development services	51,867	48,813	53,860
Total direct costs	<u>114,837</u>	<u>90,697</u>	<u>67,197</u>
Selling	39,534	23,077	13,749
General and administrative	40,463	40,109	26,538
Research and development	21,788	20,853	10,482
Depreciation	7,973	7,156	7,755
Royalty expense	1,095	-	-
Intangible asset impairment	20,600	-	-
Direct pharmaceutical start-up costs	-	-	2,123
Total operating costs and expenses	<u>246,290</u>	<u>181,892</u>	<u>127,844</u>
(Loss) income from operations	(21,313)	48,618	13,229
Other income (expense), net:			
Interest, net	(21,078)	(19,366)	(3,646)
Loss from extinguishment of debt	(1,511)	(8,053)	-
Other income (expense), net	6,697	461	(444)
	<u>(15,892)</u>	<u>(26,958)</u>	<u>(4,090)</u>
(Loss) income before income taxes	(37,205)	21,660	9,139
(Benefit from) provision for income taxes	(4,502)	8,542	3,199
Net (loss) income	<u>\$ (32,703)</u>	<u>\$ 13,118</u>	<u>\$ 5,940</u>
Basic (loss) earnings per share	<u>\$ (1.18)</u>	<u>\$ 0.48</u>	<u>\$ 0.22</u>
Weighted average shares outstanding	<u>27,730</u>	<u>27,348</u>	<u>26,691</u>
Diluted (loss) earnings per share	<u>\$ (1.18)</u>	<u>\$ 0.46</u>	<u>\$ 0.22</u>
Weighted average shares outstanding	<u>27,730</u>	<u>28,359</u>	<u>27,462</u>

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

CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	December 31,	
	2003	2002 (as restated)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,785	\$ 6,532
Accounts receivable, net	32,614	29,467
Work-in-progress	12,503	10,515
Inventories, net	14,693	17,004
Deferred tax assets	19,184	1,271
Prepaid and other current assets	10,398	6,362
Total current assets	98,177	71,151
Property and equipment, net	57,236	53,125
Goodwill, net	13,361	11,378
Intangible assets, net	351,315	281,669
Other assets	14,508	16,179
Total assets	\$ 534,597	\$ 433,502
 LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current maturities of long-term debt	\$ 4,000	\$ 5,921
Accounts payable	21,879	17,671
Customer advances	17,630	15,051
Accrued wages and benefits	5,320	6,718
Interest payable	5,511	5,232
Deferred product revenue	45,664	-
Other accrued liabilities	11,133	5,201
Total current liabilities	111,137	55,794
Long-term debt, less current portion	338,844	277,899
Deferred tax liability	2,246	3,840
Other liabilities	7,647	715
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock, \$.001 par value; 5 million shares authorized, none outstanding in 2003 or 2002	-	-
Common stock, \$.001 par value; 100 million shares authorized, 28,221,983 outstanding - 2003; 27,502,709 outstanding - 2002	28	27
Paid-in capital	88,049	79,049
Retained (deficit) earnings	(16,307)	16,396
Accumulated other comprehensive income (loss)	3,197	(218)
Deferred compensation	(244)	-
Total stockholders' equity	74,723	95,254
Total liabilities and stockholders' equity	\$ 534,597	\$ 433,502

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

aaiPharma Inc.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,		
	2003	2002 (as restated)	2001
Cash flows from operating activities:			
Net (loss) income	\$ (32,703)	\$ 13,118	\$ 5,940
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	20,246	16,395	7,755
Intangible asset impairment	20,600	-	-
Write-off of deferred financing and other costs	1,511	8,053	-
Other	434	145	1,265
Changes in operating assets and liabilities:			
Accounts receivable, net	(2,632)	(2,380)	(3,112)
Work-in-progress	(1,085)	643	6,502
Inventories, net	2,449	(7,853)	(5,452)
Deferred tax assets	(17,913)	(352)	2,597
Prepaid and other assets	(5,687)	(10,409)	(4,829)
Accounts payable	3,849	1,937	6,673
Customer advances	2,062	1,227	1,522
Interest payable	279	4,861	227
Deferred revenue	45,664	-	-
Accrued wages and benefits and other accrued liabilities	1,278	5,580	1,263
Net cash provided by operating activities	38,352	30,965	20,351
Cash flows from investing activities:			
Purchases of property and equipment	(11,910)	(8,529)	(6,315)
Purchase of property and equipment previously leased	-	(14,145)	-
Proceeds from sales of property and equipment	606	131	3,513
Acquisitions of product rights and other intangibles	(102,464)	(211,997)	(79,100)
Other	(502)	(593)	151
Net cash used in investing activities	(114,270)	(235,133)	(81,751)
Cash flows from financing activities:			
Net payments on short-term debt	-	-	(16,272)
Proceeds from long-term borrowings	160,000	244,486	78,878
Payments on long-term borrowings	(93,500)	(51,900)	(1,024)
Proceeds from interest rate swaps, net	1,703	10,486	-
Proceeds from stock option exercises	8,757	3,243	5,123
Other	1,086	(2,153)	(152)
Net cash provided by financing activities	78,046	204,162	66,553
Net increase (decrease) in cash and cash equivalents	2,128	(6)	5,153
Effect of exchange rate changes on cash	125	167	(7)
Cash and cash equivalents, beginning of year	6,532	6,371	1,225
Cash and cash equivalents, end of year	\$ 8,785	\$ 6,532	\$ 6,371
Supplemental information, cash paid for:			
Interest	\$ 24,012	\$ 16,835	\$ 2,719
Income taxes	\$ 7,248	\$ 1,346	\$ 370

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

aaiPharma Inc.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Common Stock		Paid-in Capital	Retained Earnings	Accumulated Other	Deferred Compensation	Total
	Shares	Amount		(Accumulated Deficit)	Comprehensive Income (Loss)	and Other	
Balance, December 31, 2000	26,447	\$ 27	\$ 70,352	\$ (2,662)	\$ (1,974)	\$ (22)	\$ 65,721
Stock options exercised	549	-	4,872	-	-	-	4,872
Currency translation adjustment	-	-	-	-	(672)	-	(672)
Realized loss on investments reclassified into earnings	-	-	-	-	481	-	481
Payments on stock subscriptions	-	-	-	-	-	22	22
Net income	-	-	-	5,940	-	-	5,940
Balance, December 31, 2001	26,996	27	75,224	3,278	(2,165)	-	76,364
Stock options exercised	507	-	3,825	-	-	-	3,825
Currency translation adjustment	-	-	-	-	1,837	-	1,837
Realized loss on investments reclassified into earnings	-	-	-	-	110	-	110
Net income (as restated)	-	-	-	13,118	-	-	13,118
Balance, December 31, 2002 (as restated)	27,503	27	79,049	16,396	(218)	-	95,254
Stock options exercised	719	1	8,582	-	-	-	8,583
Currency translation adjustment	-	-	-	-	3,415	-	3,415
Issuance of restricted stock award	-	-	418	-	-	(418)	-
Amortization of deferred compensation	-	-	-	-	-	174	174
Net loss	-	-	-	(32,703)	-	-	(32,703)
Balance, December 31, 2003	<u>\$28,222</u>	<u>\$ 28</u>	<u>\$ 88,049</u>	<u>\$ (16,307)</u>	<u>\$ 3,197</u>	<u>\$ (244)</u>	<u>\$ 74,723</u>

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

aaiPharma Inc.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands)

	Years Ended December 31,		
	2003	2002 (as restated)	2001
Net (loss) income	\$ (32,703)	\$ 13,118	\$ 5,940
Currency translation adjustments	3,415	1,837	(672)
Realized loss on investments reclassified into earnings from other comprehensive income	-	110	481
Comprehensive (loss) income	\$ (29,288)	\$ 15,065	\$ 5,749

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

aaiPharma Inc.
Notes to Consolidated Financial Statements
December 31, 2003

1. Significant Accounting Policies and Other Matters

Organization

aaiPharma Inc. (“aaiPharma” or the “Company”) is a science-based specialty pharmaceutical company focused on the commercialization of branded pharmaceutical products that the Company acquires or develops. The Company also has a comprehensive range of pharmaceutical development capabilities primarily in the United States and Europe. In 2003 and 2002, the majority of the Company’s net revenues came from the sale of commercial pharmaceutical products. Prior to 2002, the majority of the Company’s net revenues were earned in its development services business. Major customers for the Company’s pharmaceutical products are large, well-established medical wholesalers and distributors. Major customers for the development services and product development businesses are large and small pharmaceutical and biotechnology companies.

Basis of Presentation and Consolidation

The consolidated financial statements include the accounts of aaiPharma Inc. and its wholly-owned subsidiaries. All material intercompany transactions have been eliminated. Certain balances in the prior years’ consolidated financial statements have been reclassified to conform to the December 31, 2003 presentation.

On January 30, 2003, aaiPharma’s Board of Directors approved a three-for-two stock split of the Company’s common shares. On March 10, 2003, each stockholder received one additional share of common stock for every two shares they owned on the record date of February 19, 2003. All share and per share amounts have been restated to reflect the stock split for each period presented as if it had occurred at the beginning of the period.

Restatement of Previously Issued Financial Statements

The Company has restated its consolidated statements of operations, cash flows, stockholders’ equity and comprehensive income for the year ended December 31, 2002 and its consolidated balance sheet as of December 31, 2002. In addition, the restatement affects the first, second and third quarters of 2002 and 2003. The restated amounts for these quarters are presented in Note 13. The restatement does not affect periods prior to 2002. The restatement corrects the Company’s accounting treatment of certain transactions that did not satisfy all of the conditions of SFAS 48 or were subsequently deemed to involve subjective determinations for which the Company has determined alternative accounting treatments should be used. Set forth below are the restatement adjustments included in the restatement of the previously issued financial statements for the year ended December 31, 2002.

The following table presents the impact of the restatement adjustments described below on net income for the year ended December 31, 2002:

	Net Income for the Year Ended December 31, 2002
As previously reported	\$ 17,314
Intangible asset amortization	(6,823)
Provision for income taxes	2,627
As restated	<u>\$ 13,118</u>

The adjustments to restate the 2002 and 2003 quarterly periods relate to the following:

(i) for 2003, the correction of the Company's revenue recognition of certain transactions, including specific product sales in 2003, that did not satisfy all of the conditions for recognition of revenue under SFAS 48 and/or SAB 101, as well as significant increases in reserves for product returns and other adjustments to the Company's revenue and product inventory reserves, and

(ii) for 2002 and 2003 a change in the accounting treatment used with respect to the Company's product line acquisitions from accounting for the acquisitions as business combinations to recording such transactions as asset acquisitions. Accordingly the Company adjusted the related allocations to reverse the recording of goodwill and allocate all amounts specifically to identifiable tangible and intangible assets (see note 2).

The following table presents the impact of the restatement adjustments on the Company's previously reported results for the year ended December 31, 2002 on a condensed basis:

	Year Ended December 31, 2002	
	As Previously Reported	As Restated
Statement of operations:		
Net revenues	\$ 230,510	\$ 230,510
Total costs and expenses	213,196	217,392
Net income	<u>\$ 17,314</u>	<u>\$ 13,118</u>
Basic earnings per share	<u>\$ 0.63</u>	<u>\$ 0.48</u>
Diluted earnings per share	<u>\$ 0.61</u>	<u>\$ 0.46</u>

December 31, 2002

	As Previously Reported	As Restated
(In thousands)		
Balance sheet:		
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,532	\$ 6,532
Accounts receivable, net	29,467	29,467
Other current assets	35,152	35,152
Total current assets	71,151	71,151
Other assets	369,174	362,351
Total assets	\$ 440,325	\$ 433,502

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities	\$ 55,794	\$ 55,794
Long-term debt, less current portion	277,899	277,899
Other liabilities	7,182	4,555
Stockholders' equity	99,450	95,254
Total liabilities and stockholders' equity	\$ 440,325	\$ 433,502

Subsequent Events

NASDAQ Delisting

The Company received notice on March 30, 2004 from the NASDAQ Stock Market that, due to the delay in filing of its Form 10-K for the fiscal year ended December 31, 2003, the Company is not in compliance with certain NASDAQ marketplace rules and that its common stock would be subject to delisting at the opening of business on April 8, 2004, unless the Company request a hearing pursuant to NASDAQ rules. The Company requested and participated in a hearing before NASDAQ on April 29, 2004 in which it committed to filing this Report on Form 10-K on or before June 15, 2004 and to file amended quarterly Reports on Form 10-Q for each of the three quarters of 2003 on or before June 30, 2004. The Company has not received notification of the outcome of the delisting hearing. On May 18, 2004, the Company received notice from the NASDAQ Stock Market that the Company was delinquent on the filing of its Form 10-Q for the period ended March 31, 2004.

Credit Ratings Downgrade

On March 31, 2004, each of Moody's Investors Service and Standard & Poor's Ratings Services announced that it had lowered the Company's corporate credit rating: Moody's to Caa2 from B2 and Standard & Poor's to CCC from B+. At the same time, Moody's lowered its rating of aaiPharma's senior subordinated notes to Ca from Caal and aaiPharma's senior unsecured issuer rating to Caa3 from B3. Standard & Poor's lowered its senior secured debt rating to CCC+ from BB-, and its subordinated debt rating to CC from B-.

Senior Credit Agreement and Indenture Defaults

aaPharma did not file its Annual Report on Form 10-K for the year ended December 31, 2003 (the "2003 Form 10-K") in the time required by the federal securities laws. This failure to file the 2003 Form 10-K constituted an event of default under its former senior credit agreement, dated as of March 28, 2002 (as amended, the "Credit Agreement"), with Bank of America, N.A. as administrative agent (in such capacity, the "Administrative Agent"). Due to this and other events of default under the Credit Agreement, the Company was advised by the Administrative Agent that the Company was not permitted to make any borrowings under the \$100 million revolving credit facility portion of the Credit Agreement.

On April 23, 2004, aaPharma refinanced the Credit Agreement with \$140 million of senior credit facilities with a syndicate of lenders, Silver Point Finance LLC as collateral agent, and Bank of America, N.A., as administrative agent (the "Restructured Facility"). The Restructured Facility consists of a two-year, \$125 million senior secured term loan facility (which was fully drawn at closing) and a two-year, \$15 million senior secured revolving credit facility.

M.V.I. and Aquasol Sale

On April 26, 2004, the Company sold its M.V.I. and Aquasol product lines to Mayne Pharma (USA) Inc. for \$105 million, subject to adjustments based on inventory levels at closing and other post-closing obligations (the "M.V.I. and Aquasol Sale"). A portion of the closing payment is held in escrow to satisfy post-closing obligations under the agreement. At the closing of the transaction, the Company paid to AstraZeneca AB the \$31.5 million payment due in August 2004 (see Note 2), which was discounted to approximately \$31.0 million as a result of the early payment (the "M.V.I. Payment").

Royalties Receivable

The Company entered into a definitive agreement to receive a prepayment of certain royalties receivable (the "Accelerated Royalties"), that would otherwise have been paid to it quarterly through the second quarter of 2005 pursuant to the development agreement discussed below under "Revenue Recognition – Product Development." These royalties would have aggregated \$15.4 million. The agreement to receive a prepayment of these royalties discounted the Accelerated Royalties by 5% per annum from the date originally due to the advance payment date. The Company received approximately \$15.0 million in gross proceeds from the Accelerated Royalties in April 2004.

Termination of Interest Rate Hedging Obligation

At December 31, 2003 aaPharma was a party to an interest rate hedging agreement to effect a swap of its fixed interest rate on a notional amount of the Company's 11% senior subordinated notes (the "Notes," see Note 6) to a floating interest rate. The Company terminated the interest rate hedging agreement. The Company's termination obligations under this interest rate hedging agreement were approximately \$9.4 million, which were paid in full on April 26, 2004.

Governmental Investigations and Litigation

In April 2004, the Company received subpoenas for document production and potential testimony issued by a grand jury of the U.S. District Court for the Western District of North Carolina related primarily to 2002 and 2003 financial information, certain loans obtained by it, extensions of credit, and other information. The Company has also been advised by the Office of the United States Attorney for the Western District of North Carolina that it may receive a subpoena from the Securities and Exchange Commission ("SEC"). In addition, the Company and certain of its current and former officers and employees have been named as defendants in

multiple purported class action lawsuits commenced by stockholders and retirement plan participants beginning in February 2004 alleging violations of federal securities laws and ERISA.

Revenue Recognition

The Company recognizes revenue in accordance with the SEC's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" as amended by Staff Accounting Bulletin No. 104 (together, "SAB 101"), and FASB Statement No. 48 "Revenue Recognition When Right of Return Exists" ("SFAS 48"). SAB 101 states that revenue should not be recognized until it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. SFAS 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if (1) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated.

Net Revenues

The Company's net revenues represent the Company's total revenues less allowances for customer credits, including estimated discounts, rebates, chargebacks, product returns and non-research and development expenses reimbursed by customers.

Net revenues are reported for the Company's three operating segments, which are product sales, development services and product development.

Product Sales

The Company recognizes revenues for product sales at the time title and risk of loss are transferred to the customer, and the other criteria of SAB 101 and SFAS 48 are satisfied, which is generally at the time products are shipped. Product shipping and handling costs are included in product cost of goods sold. Products are sold to pharmaceutical wholesalers, the largest three of which account for approximately 81% and 88% of the Company's sales revenues for the years ended December 31, 2003 and 2002, respectively. At the time gross revenue is recognized from product sales, an adjustment, or decrease, to revenue for estimated chargebacks, rebates, discounts and returns is also recorded. These revenue reserves are determined on a product-by-product basis. Revenue reserves are established by management as its best estimate at the time of sale based on each product's historical experience adjusted to reflect known changes in the factors that impact such reserves. Reserves for chargebacks, rebates and related allowances are established based on the contractual terms with customers; analysis of historical levels of discounts, chargebacks and rebates; communications with customers and purchased information about the rate of prescriptions being written and the levels of inventory remaining in the distribution channel as well as expectations about the market for each product and anticipated introduction of competitive products. The reserve for chargebacks is the most significant estimate used in the recognition of revenue from product sales. Contract prices are established for certain indirect customers that are supplied by the Company's wholesale customers. A chargeback represents the difference between the current published wholesale acquisition cost and the indirect customer's contract price. If the actual amount of cash discounts

taken, chargebacks, rebates and expired product returns differ from the amounts estimated by management, material differences may result from the amount of revenue the Company recognizes from product sales.

In the case of shipments made to wholesalers that do not meet the revenue recognition criteria of SFAS 48, and SAB 101, such shipments are accounted for using the consignment model. Product shipments accounted for under the consignment model currently include the Company's new product launches in 2003 and product shipments through a new specialty distributor, which began in the third quarter of 2003. Under the consignment model, the Company does not recognize revenue upon shipment of product. For these product sales, the Company invoices the wholesaler, records deferred revenue at gross invoice sales price, and classifies the inventory held by the wholesaler as "consigned inventory" at the Company's cost of goods for such inventory. The Company recognizes revenue on consigned inventory when such inventory is sold through to the wholesalers' customers, on a first-in first-out (FIFO) basis. The Company's estimates of inventory at the wholesalers and deferred revenue on consigned inventory are based on (1) the projected prescription demand-based sales for its products, (2) the Company's analysis of third-party information, including information obtained from certain wholesalers with respect to their inventory levels and sell-through to customers and third-party market research data, and (3) the Company's internal product sales information. The Company's estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information was itself in the form of estimates, and reflect other limitations. The Company's sales and revenue recognition for such consigned inventory reflect the Company's estimates of actual product sold through to the wholesale customer. As of December 31, 2003, deferred product revenues under the consignment model were \$45.7 million.

Prior to 2003, the amount of actual product returns experienced by the Company had not been significant. As a result, actual returns were charged against revenue in the period they occurred and aggregate revenue reserves were evaluated quarterly to determine if they were sufficient to cover estimated chargebacks, rebates and related allowances, as well as the expected rate of returns, and adjusted as deemed necessary. In 2003, the Company began segregating the Company's products return reserve, which prior thereto the Company believed was adequately covered by the Company's aggregate revenue reserves for chargebacks, rebates and related allowances. The Company increased the level of detail included in the Company's analyses to include analyzing inventory in the channel to determine remaining shelf life. The Company's returns reserve needs are primarily related to the number of months of inventory estimated to be in the distribution channel. Levels of inventory in the distribution channel are monitored and estimated based on information the Company purchases from the wholesalers, combined with active discussions between the Company's sales personnel and the wholesalers to which the Company supplies. In addition, the Company's actual sales, returns and chargeback history are used to assess the reasonableness of the estimated number of months of inventory on hand at the Company's wholesalers. The shelf life of products remaining in the distribution channel is estimated based on an analysis of each lot sold. Each batch has a specific expiration date. A review of the actual returns history is performed and the run rate of sales out of the distribution channel is estimated. Estimated product returns reserves are adjusted based on these reviews. Reserves may also be adjusted to reflect any significant changes in trends or based upon new information that the Company believes may affect the reserve needs. Allowances for new product introductions are estimated based on the Company's experiences for similar products that the Company currently markets and are adjusted as deemed necessary based on the Company's experience with each product. The Company's reserve analysis also includes a review for the potential introduction of generic competition and the resulting impact on pricing and returns reserves. Existing reserves may be adjusted accordingly to reflect the Company's estimate for any impact these factors may have. aaiPharma continually monitors its assumptions with respect to the Company's revenue reserves for product sales and modifies them if necessary.

Product Development

The majority of the product development segment's revenues consist of licensing, milestone and royalty payments from the Company's proprietary technology. The provisions for licensing, milestone and royalty payments included in contracts are related to the occurrence of specific identifiable events. Each of the licensing agreements is reviewed to determine the appropriate revenue recognition treatment under SAB 101 and EITF 00-21 "Revenue Arrangements with Multiple Deliverable Arrangements." The Company recognizes revenues from licensing fees over the estimated life of the agreement to which the licensing fees relate or when the commitment to perform services under the agreement has been fulfilled. Milestone payments are recognized as revenue when the milestone has been achieved, the performance obligation has been met and collection of the milestone-related revenue to be recognized is probable. The Company recognizes recurring royalties revenue in the period in which the related product sales occur or, in the case of the development agreement discussed below, in the period the matching contractual obligation is performed.

The Company has a development agreement with a customer that provides for it to receive contingent periodic royalties and obligates the customer to use the Company on a fee-for-service basis for a product life cycle management project related to the product. The customer is a major pharmaceutical company with net assets in excess of \$2.0 billion. The development agreement relates to a product with respect to which the Company has licensed intellectual property that it developed in the past. The Company has recognized product development revenues under this agreement for the periodic payments based on its customer's sales of the product, and have recognized development services revenue related to the product life cycle management project. Product development revenues from this agreement were \$13.0 million in 2003, \$16.9 million in 2002 and \$14.9 million in 2001. The Company recognized no research and development expense in 2003, 2002 and 2001 associated with the payments it received in those years. The expense of its work associated with these revenues was recognized primarily in 1997 through 1999. The Company does not anticipate incurring significant expense associated with the product development revenues under this agreement in future periods. Development services revenue associated with this agreement were \$2.7 million in 2003, \$4.7 million in 2002 and \$6.3 million in 2001. Because of the research and development nature of its activities in this product life cycle management project and the potential that these activities could result in continuation of product development revenues into the future, the Company has recorded its costs incurred in this project as research and development expense--\$1.0 million in 2003, \$0.7 million in 2002 and \$2.3 million in 2001. Accordingly, for its development services business unit, the Company has recognized no expense associated with the development services revenue arising under this agreement, as this expense was recognized by its product development business unit.

The Company is entitled to receive these periodic royalties based on sales of the customer's product only if it makes available exclusively to its customer its product development and reformulation services with respect to a limited group of drugs that include the customer's product. This obligation does not prevent the Company from engaging in these development and reformulation activities for products that it may develop for itself. As the Company remains available to provide the customer with these services on this basis in a calendar quarter, it will be entitled to royalties based on the level of sales over a prior monthly period of the product. The customer is obligated to make these quarterly payments based on whether defined market events have occurred in the prior measurement month--e.g., if the defined market events have not occurred during three consecutive months, the Company would be entitled to royalties in three consecutive quarters, with, for example, the amount of the royalties in the first quarter being based on product sales in the first month. However, if it does not continue to provide these development and reformulation services on the exclusive basis described above in any quarter, it will not be entitled to the royalties for that quarter and all subsequent quarters. Under the agreement, the

Company has the right, at any time, to terminate its obligation to provide the development and reformulation services on an exclusive basis. Accordingly, the Company does not recognize product development revenues under this agreement in any quarter until it has satisfied the exclusivity requirement for that quarter.

Development Services

The Company recognizes the majority of its development services revenues from fee-for-service contracts on a proportional performance basis as the work is performed. To measure performance, the Company compares actual direct costs incurred to estimated total contract direct costs, which is the best indicator of performance of the contract obligations as the costs directly relate to the labor hours incurred to perform the service. This ratio is multiplied by the estimated contract value to determine the revenue to be recognized. The proportional performance method requires an estimate of total expected revenue and at no time under this method are costs deferred. These estimates are reviewed periodically and, if these estimates change or actual results differ from expected results, an adjustment is recorded in the period in which they become reasonably estimable. These adjustments could have a material effect on the Company's results of operations. Historically, there have not been significant variations between contract estimates and actual costs incurred. Changes in the scope of work generally result in an amendment to contract pricing terms. Amended contract amounts are not included in net revenues until signed change orders are executed, revenue is earned and realization is assured. The Company also recognizes revenue on a time and materials basis in accordance with the specific contract terms. Revenues recognized prior to contract billing terms are recorded as work in progress.

The majority of the Company's arrangements with customers are not multiple-element arrangements. However, due to the proprietary nature of product formulations, the Company has entered into a limited number of multiple-element arrangements related to product development activity. During 2003, the Company adopted EITF 00-21 and has applied its criteria to such arrangements in determining the separability of elements and timing of revenue recognition under SAB 101.

Provisions for losses on contracts, if any, are recognized when identified. Clients generally may terminate services at any time. However, the majority of contracts contain provisions that require payment for all services rendered to date, even those services that had not yet been billed. In the specific cases where these termination provisions are not specifically defined in the contract, the Company ensures that the future billing milestones are achievable and within the Company's control prior to recognition of revenue under such arrangements

The following table sets forth the Company's gross revenues and the amount of dilution to revenues resulting from revenue reserves such as allowances for customer credits, including discounts, rebates, chargebacks, product returns and other allowances for each of 2003, 2002 and 2001:

	Years Ended December 31,		
	2003	2002 (as restated) (in thousands)	2001
Gross revenues	\$ 327,282	\$ 283,914	\$ 150,115
Allowance for customer credits	<u>102,305</u>	<u>53,404</u>	<u>9,042</u>
Net revenues	<u>\$ 224,977</u>	<u>\$ 230,510</u>	<u>\$ 141,073</u>

Income Taxes

Income taxes have been accounted for using the liability method in accordance with Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards No. 109 "Accounting for Income Taxes." This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of differences between the tax basis of assets or liabilities and their carrying amounts in the consolidated financial statements. A valuation allowance is provided for deferred tax assets if it is more likely than not that these items will either expire before the Company is able to realize their benefit or if future deductibility is uncertain. Developing the provision for income taxes requires significant judgment and expertise in federal and state income tax laws, regulations and strategies, including the determination of deferred tax assets and liabilities and, if necessary, any valuation allowances that may be required for deferred tax assets. The Company's judgments and tax strategies are subject to audit by various taxing authorities. While the Company believes that it has provided adequately for its income tax liabilities in its consolidated financial statements, adverse determinations by these taxing authorities could have a material adverse effect on the Company's consolidated financial condition and results of operations.

Research and Development Costs

The Company engages in numerous research and development ("R&D") projects with the objective of growth and utilization of its portfolio of proprietary technologies and patent and intellectual property rights to bring products to market or to license or sell these technologies to others. R&D expenses represent direct salaries of R&D personnel, raw material expenses, third-party consulting and testing costs, along with an allocation of indirect costs such as management and administrative overhead costs and facilities costs. R&D costs are charged to expense as incurred. Although there is a risk that any specific R&D project may not produce revenues, the Company believes that the potential profit margins from successful development projects will compensate for costs incurred for unsuccessful projects. The Company is currently involved in many pharmaceutical and technology development projects and believes that these activities help to diversify its R&D portfolio and manage its risk.

Advertising

The Company expenses advertising costs as incurred, and these costs are included in selling expenses. Advertising costs were \$8.0 million, \$4.5 million and \$0.9 million for the years ended December 31, 2003, 2002 and 2001, respectively.

(Loss) Earnings per Share

Basic (loss) earnings per share is based on the weighted average number of common shares outstanding during the year. Diluted (loss) earnings per share is computed assuming that the actual weighted average number of common shares outstanding was increased by the exercise of stock options issued to employees and members of the Company's Board of Directors under the treasury stock method. The diluted per share amounts reflect a change in the number of shares outstanding (the "denominator") to include the options as if they were exercised and converted to shares and issued, unless their inclusion would be anti-dilutive. In 2003, 2002 and 2001, 1,890,548, 2,296,001 and 824,378 options were excluded as they were anti-dilutive. In each year presented, the net (loss) income (the "numerator") is the same for both basic and diluted per share computations.

The following table provides a reconciliation of the denominators for the basic and diluted earnings per share computations:

	Years Ended December 31,		
	2003	2002 (as restated) (In thousands)	2001
Basic earnings per share:			
Weighted average number of shares	27,730	27,348	26,691
Effect of dilutive securities:			
Stock options	-	1,011	771
Diluted earnings per share:			
Adjusted weighted average number of shares and assumed conversions	27,730	28,359	27,462

Concentration of Credit Risk

The Company is subject to a concentration of credit risk with respect to its accounts receivable balance, all of which is due from wholesalers, distributors and large and small pharmaceutical and biotechnology companies. At December 31, 2003, approximately 29% of the accounts receivable balance represented amounts due from one customer. At December 31, 2002, approximately 18% and 17%, respectively, of the accounts receivable balance represented amounts due from two customers. At December 31, 2001, no single customer accounted for more than 10% of the Company's accounts receivable balance. The Company performs ongoing credit evaluations of its customers and maintains reserves for potential uncollectible accounts. Actual losses from uncollectible accounts have been minimal.

In 2003, three customers accounted for approximately 17%, 15% and 12%, respectively, of the Company's revenues. In 2002, three customers accounted for approximately 19%, 18% and 12%, respectively, of the Company's revenues. One customer accounted for approximately 15% of the Company's revenue in 2001.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents.

Work-in-Progress

Work-in-progress represents revenues recognized prior to contract billing terms.

Inventories

Inventories are stated at the lower of cost (determined on a first-in, first-out basis) or market.

The changes in identifiable intangible assets for the years ended December 31, 2003 and 2002 are as follows:

	Balance at January 1, 2003	Additions	Amortization Expense	Asset Impairment	Balance at December 31, 2003	Amortizable Life
	(in thousands)					
Indefinite-lived intangibles	\$ 51,017	\$ -	\$ -	\$ -	\$ 51,017	Indefinite
Trademarks, technology and license agreements	230,652	103,670	(12,620)	(21,404)	300,298	3 - 20 years
	<u>\$ 281,669</u>	<u>\$ 103,670</u>	<u>\$ (12,620)</u>	<u>\$ (21,404)</u>	<u>\$ 351,315</u>	
	Balance at January 1, 2002	Additions	Amortization Expense (as restated, in thousands)	Balance at December 31, 2002	Amortizable Life	
Indefinite-lived intangibles	\$ 51,017	\$ -	\$ -	\$ 51,017	Indefinite	
Trademarks, technology and license agreements	27,824	212,349	(9,521)	230,652	3 - 20 years	
	<u>\$ 78,841</u>	<u>\$ 212,349</u>	<u>\$ (9,521)</u>	<u>\$ 281,669</u>		

The total intangible asset amortization expense for the year ended December 31, 2003, was \$12.6 million, of which \$12.3 million is product related and is included in direct costs and \$0.3 million, which is included in depreciation and amortization expenses. Amortization expense for the next five years is estimated to be approximately \$19 million per year.

In December 2001, the Company acquired the Brethine product line, as further discussed in Note 2. In early 2004, generic versions of this product were approved by the FDA. In December 2003, the Company performed an analysis of the carrying value of the intangible assets associated with the product, based on discounted cash flows using its updated assumptions, and determined that they were impaired. The Company recorded an impairment charge of \$15.9 million.

In July 2003, the Company acquired the rights to a product marketed under the Darvocet A500 brand name. The Company initially valued these rights at \$4.7 million, and recorded such value as an intangible asset to be amortized over its estimated useful life. As a result of a delay in market acceptance of the Darvocet A500 product and other changes in market condition for these products, the Company evaluated the intangible asset carrying value at December 31, 2003. Based on a discounted cash flows analysis of this intangible as of December 31, 2003, the Company determined that the value was fully impaired and wrote off the unamortized balance of \$4.7 million as intangible asset impairment on the consolidated statements of operations.

On a periodic basis, or as otherwise required, the Company assesses the value of its goodwill, intangibles and other assets by determining their ability to recover the unamortized balances over the remaining useful lives. Goodwill, intangibles and other long-lived assets determined to be unrecoverable are written-off in the period in which such determination is made. The Company has changed its annual test date from December 31st to October 1st for testing whether goodwill is impaired. This change is both preferable and allowed in that choosing the 1st day of the 4th quarter allows adequate time to perform the first step of the test and, if necessary, the second step of the test while still providing time to report the impact of the test in the Company's periodic filings. The Company will test goodwill for impairment as of October 1st of each fiscal year, or more frequently should circumstances change or events occur that would more likely than not reduce the fair value of a reporting unit below its carrying amount, as provided for in SFAS No. 142.

Foreign Currency Translation

The financial statements of foreign subsidiaries have been translated into U.S. dollars in accordance with Statement of Financial Accounting Standards No. 52 "Foreign Currency Translation." All balance sheet accounts have been translated using the exchange rates in effect at the balance sheet dates. Income statement amounts have been translated using the average exchange rates for the respective years. The gains and losses resulting from the changes in exchange rates from year to year have been reported in accumulated other comprehensive income (loss) included in the consolidated statements of stockholders' equity.

Derivative Financial Instruments

aaPharma used an interest rate hedging agreement to modify its fixed rate obligation under the Notes to a variable rate obligation, thereby adjusting the interest rate to the current market rate and ensuring that the hedged notional amount of the debt instrument is always reflected at fair value. The Company follows Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities", as amended ("SFAS 133"), to account for its interest rate swap using hedge accounting treatment. As of December 31, 2003, the Company had outstanding one interest rate hedging agreement to convert a portion of fixed rate debt to a floating rate basis, thus hedging for changes in the fair value of the fixed rate debt being hedged. The Company has determined that this interest rate hedging agreement, designated as a fair value hedge, qualifies for treatment under the short-cut method of measuring effectiveness. Under the provisions of SFAS 133, this hedge is determined to be "perfectly effective", and there is no requirement to periodically evaluate effectiveness. See Note 6 for additional details on the outstanding interest rate hedging agreement. This interest rate hedging agreement was terminated in April 2004.

Impact of Recently Issued Accounting Standards

In 2003, the Company adopted Statement of Financial Accounting Standards No. 145, "Rescission of FASB Statements 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" ("SFAS 145"). SFAS 145 no longer requires companies to report gains or losses associated with the extinguishment of debt as a component of extraordinary gains or losses, net of tax. In addition, any extraordinary gains or losses on extinguishment of debt in prior periods presented would require reclassification. As required by SFAS 145, the extraordinary loss recognized in the year ended December 31, 2002 of approximately \$8.1 million (\$5.3 million net of tax) to record the write-off of deferred financing and other costs related to its prior debt facilities has been reclassified to other expense.

Statement of Financial Accounting Standards No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"), requires that a liability for costs associated with an exit or disposal activity be recognized when the liability is incurred rather than when a commitment to an exit plan is made. SFAS 146 is effective for exit or disposal activities that are initiated after December 31, 2002. Adoption of this statement did not have a material effect on its financial position or results of operations.

In January 2003, the FASB issued Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities." FIN 46 requires an investor with a majority of the variable interests (primary beneficiary) in a variable interest entity (VIE) to consolidate the entity and also requires majority and significant variable interest investors to provide certain disclosures. A VIE is an entity in which the voting equity investors do not have a controlling interest, or the equity investment at risk is insufficient to finance the entity's activities without receiving additional subordinated financial support from other parties. Effective December 2003, the FASB issued Staff Position FIN 46R that defers the application of FIN 46 to interests in potential VIEs if the VIE was created prior to February 1 2003 and the company has not issued financial statements reporting interests in VIEs in accordance with FIN 46 until the end of periods ending after March 15, 2004. The Company adopted FIN 46 in fiscal 2003 and the adoption did not have a significant impact on the Company's consolidated financial position, results of operations or cash flows.

Other recently issued, but not yet effective, accounting standards will not have a material impact on the Company.

Employee Stock-Based Compensation

The Company follows Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related Interpretations in accounting for its employee stock options as permitted by Statement of Financial Accounting Standards No. 123 "Accounting for Stock-Based Compensation" ("SFAS 123") and makes the pro forma disclosures required by SFAS 123, as amended by SFAS 148, "Accounting for Stock-Based Compensation-Transition and Disclosure."

The fair value for stock options was estimated at the date of grant using a Black-Scholes pricing model with the following weighted average assumptions:

	<u>Years Ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Expected dividend yield.....	0.0%	0.0%	0.0%
Risk-free interest rate.....	3.0%	3.8%	4.6%
Expected volatility	116.0%	113.0%	120.0%
Expected life (in years from vesting)	5	5	5

For purposes of pro forma disclosures, the estimated fair value of the stock options is amortized to expense on a straight-line basis over the vesting period. The grant date Black-Scholes weighted average fair value of options issued at market price was \$13.19, \$11.49 and \$8.90 per share for 2003, 2002 and 2001, respectively, and the weighted average fair value of options issued in excess of market price was \$9.94 per share in 2002. No options were issued in excess of market price in 2003 or 2001.

The Company applies APB 25 and related Interpretations in accounting for its stock option plans; therefore, compensation expense has not been recognized for options granted at fair value. If compensation cost for the Company's stock option plans had been determined based on the fair value at the grant dates for awards under those plans consistent with the fair value method of SFAS 123, the Company's net (loss) income and earnings (loss) per share would have been changed to the pro forma amounts indicated below. Pro forma compensation expense under SFAS 123 is based on the single award method recorded on a straight-line basis.

	Years Ended December 31,		
	2003	2002 (as restated)	2001
(In thousands, except per share data)			
Net (loss) income, as reported	\$ (32,703)	\$ 13,118	\$ 5,940
Deferred compensation amortization, net of tax	104	-	-
Pro forma stock-based compensation cost, net of tax	9,764	6,520	2,366
Pro forma net income (loss)	(42,363)	6,598	3,574
Earnings (loss) per share:			
As reported -			
Basic	\$ (1.18)	\$ 0.48	\$ 0.22
Diluted	\$ (1.18)	\$ 0.46	\$ 0.22
Pro forma -			
Basic	\$ (1.53)	\$ 0.24	\$ 0.13
Diluted	\$ (1.53)	\$ 0.23	\$ 0.13

Fair Value of Financial Instruments

The carrying values of cash and cash equivalents, accounts receivable, work-in-progress and current liabilities approximate fair values as of December 31, 2003 and 2002. Based on borrowing rates currently available to the Company, the carrying value of the variable rate debt approximated fair value. The fair market value of the Company's fixed rate debt is based on market quotations. At December 31, 2003 and 2002, the fair market value of the Company's fixed rate debt was approximately the carrying value.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The most significant estimates relate to revenue reserves and sales allowances, including reserves for chargebacks, product returns, rebates and related allowances, an allowance for doubtful accounts, inventory reserves and useful lives for intangible assets. Actual results could differ from such estimates and changes in such estimates may have a material effect on amounts reported in future periods.

2. Asset Acquisitions

On December 2, 2003, the Company acquired a line of pain management products, which treat moderate to severe pain, (the "New Pain Products") and existing inventory from subsidiaries of Elan Corporation, plc, in an asset purchase. The product lines acquired are marketed under the Roxicodone, Oramorph SR, Roxanol and Duracloñ brand names. The Company acquired these product lines and related intangible assets for \$102.5 million, exclusive of transactional costs. To finance this acquisition, which included \$5.1 million of inventory, the Company used the proceeds from its then-existing senior term loan credit facility, as described in Note 6. Revenues from the sales of these products are included in the Company's results of operations beginning on the acquisition date. The New Pain Products did not have separable assets and liabilities associated with them, other than inventory. Therefore the Company allocated the purchase price, including acquisition related expenses, to acquired identifiable tangible and intangible assets. Based on this allocation, \$98 million of intangible assets have been identified and will be amortized over 20 years.

The following unaudited pro forma consolidated financial information reflects the results of operations for the years ended December 31, 2003 and 2002 as if the acquisition of the New Pain Products had occurred at the beginning of the periods presented.

	Years Ended December 31,	
	2003	2002
	(In thousands, except per share data)	
Net revenues	\$ 294,895	\$ 295,592
Direct costs	120,498	98,152

These pro forma results have been prepared for comparative purposes only and do not purport to be indicative of what operating results would have been had the acquisition taken place at the beginning of the period presented. In addition, these results are not intended to be a projection of future results.

On August 5, 2003, aaiPharma and CIMA LABS INC., ("CIMA") entered into a merger agreement. The completion of the merger was subject to several conditions, including the approval of the merger by the stockholders of CIMA and aaiPharma and the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and contained customary termination rights by each party in the event of higher unsolicited offers by a third party. During the fourth quarter of 2003, the Company announced the termination of the merger agreement by CIMA in light of a competing offer for CIMA by a third party. As a result, the Company received an \$11.5 million termination fee from CIMA, as provided in the terminated merger agreement, against which \$5.9 million of merger-related fees and expenses were applied. The net amount of \$5.6 million is included in other income on the consolidated statements of operations.

On March 28, 2002, the Company acquired the U.S. rights to the Darvon and Darvocet branded product lines, which treat mild-to-moderate pain, and existing inventory from Eli Lilly and Company, in an asset purchase. The Company acquired these product lines and related intangible assets for \$211.4 million, exclusive of transactional costs. To finance this acquisition, which included \$1.8 million of inventory, the Company used the proceeds from the then existing senior secured credit facilities and senior subordinated notes, as described in Note 6. Revenues from the sales of these products are included in the Company's results of operations beginning

on the acquisition date. The Darvon and Darvocet product lines did not have separable assets and liabilities associated with them, other than inventory, therefore the Company allocated the purchase price, including acquisition related expenses, to acquired identifiable tangible and intangible assets. The identified intangible assets are amortized over 20 years.

In December 2001, the Company acquired from Novartis Pharmaceutical Corporation and Novartis Corporation a line of asthma products used in the prevention and reversal of bronchospasm in patients age 12 and older with asthma and reversible bronchospasm associated with bronchitis and emphysema, in an asset purchase. The product line acquired is marketed under the Brethine brand name. The Company acquired this product line and related intangible assets for \$26.6 million, exclusive of transactional costs. To finance this acquisition, the Company used the proceeds from a \$25 million term loan, which was refinanced in March 2002 by a senior secured credit facility as described in Note 6, and used working capital to pay the remainder of the purchase price. Revenues from the sales of these products are included in the Company's results of operations beginning on the acquisition date. The Brethine product line did not have separable assets and liabilities associated with it, therefore the Company allocated the purchase price, including acquisition related expenses, to acquired identifiable intangible assets, which are being amortized over 20 years.

In August 2001, the Company completed the acquisition of a line of critical care injectable and oral nutrition products from AstraZeneca AB, an affiliate of AstraZeneca PLC, in an asset purchase. The product lines acquired are marketed under the M.V.I. and Aquasol brand names. The Company acquired these product lines and related intangible assets for \$52.5 million, exclusive of transactional costs, paid at closing, plus additional consideration described below. To finance the initial payment for this acquisition, which included \$3.7 million for inventory, the Company used the proceeds from a term loan, which was refinanced by a senior secured credit facility as described in Note 6. The product line acquisition agreement was amended in July 2003. As amended, it provided for two \$1.0 million guaranteed payments, which were made in August 2002 and 2003, eliminated a contingent payment of \$2.0 million that was potentially due in August 2003 under the original agreement, and provided for a future contingent payment of \$43.5 million potentially due in August 2004, depending on the status of certain reformulation activities being carried out by the seller and regulatory approval of the reformulations by the U.S. Food and Drug Administration (FDA). The amount of the \$43.5 million contingent payment was to be reduced by \$1 million per month if the conditions for the contingent payment had not occurred by December 31, 2002. The amount of the contingent payment had decreased by \$12.0 million by December 31, 2003. Such conditions were satisfied in January and February 2004, fixing the previously contingent liability under the amendment at \$31.5 million. As a result of the July 2003 amendment to the original purchase agreement, the Company was precluded from recognizing this obligation as additional purchase price for the M.V.I. and Aquasol product line. As of December 31, 2003, this contingent obligation had not been recorded as a liability on the Company's consolidated balance sheet and will be recorded as a liability and as an other expense in the first quarter of 2004. Also in July 2003, the M.V.I. supply agreement with the seller was extended through 2008, subject to early termination rights by the Company on six months' notice given at any time, and by the supplier on twenty-four months notice given at any time on or after August 17, 2004. Revenues from the sales of these products are included in the Company's results of operations beginning on the acquisition date. The M.V.I. and Aquasol product lines did not have separable assets and liabilities associated with them, other than inventory; therefore the Company allocated the purchase price, including acquisition related expenses, to acquired identifiable tangible and intangible assets.

In connection with the M.V.I. and Aquasol acquisition, the Company recorded intangible assets which meet the criteria for having an indefinite life. In accordance with SFAS 142, these intangible assets are not being

amortized but are evaluated for impairment on at least an annual basis. The intangible assets recorded in connection with this acquisition represent the trademarks, technology and know-how associated with the product lines.

On April 26, 2004, the Company sold the M.V.I. and Aquasol product lines to Mayne Pharma (USA) Inc., for \$105 million subject to certain adjustments based on inventory levels at closing and other post-closing obligations. A portion of the closing payment is held in escrow to satisfy the Company's post-closing obligations under the agreement. At the closing of the transaction, aaiPharma paid to AstraZeneca AB the \$31.5 million payment due in August 2004, which was discounted to approximately \$31.0 million (the "M.V.I. Payment"). Royalties on sales levels of the new M.V.I. product formulation above specified thresholds will be paid to the Company as part of this agreement.

During July 2001, the Company made an initial payment of \$0.9 million to acquire the assets of a sterile manufacturing facility located in Charleston, South Carolina. In 2002, a \$0.2 million payment was made based on the level of manufacturing revenues at this facility. No payment was made in 2003. Additional contingent payments of up to \$4.8 million plus additional royalties may become due in increments through June 30, 2006 based on the level of manufacturing revenues during this period. These contingent payment obligations have not yet been recorded as a liability on the Company's consolidated balance sheets.

Set forth in the table below are the details of the purchase price allocations for each of the Company's major product line acquisitions since the beginning of 2001. The table lists the assets acquired, the value allocated to each asset, how the value was determined, and the estimated useful life assigned to each asset. In these acquisitions, the only tangible assets acquired were inventory and marketing/promotional materials, which were valued based on internal analyses and data provided by the sellers. Inventory obtained at time of acquisition was valued at the estimated selling price less the cost of disposal and a reasonable selling profit. Marketing/promotional materials received were generally outdated and in limited quantities; therefore no material value was assigned in the purchase price allocations. The Company engaged third-party valuation consultants to assist the Company with its purchase price allocations, including identification of intangible assets recommendations of fair value of intangible assets, and determination of expected lives of those assets. Intangible assets that arose from contractual or legal rights and other intangible assets that were separable, as discussed in SFAS 141, were identified. Among the assets that were considered for recognition were trademarks, Internet domain names, non-competition agreements, customer lists, backlogs, customer contracts and non-contractual relationships, licensing and royalty agreements, supply contracts, employment contracts, patented and unpatented technology, and trade secrets.

The third-party valuation consultants reviewed pertinent facts and recommended for each asset the appropriate generally accepted valuation approach and methodology from among the cost, market, and income approaches. Where possible, a valuation derived using an alternative valuation approach or methodology was presented and used by management to evaluate the reasonableness of the recommended fair value.

<u>Identifiable Assets</u>	<u>Value (millions)</u>	<u>How Valued</u>	<u>Useful Life</u>
M.V.I. and Aquasol (as restated):			
Total purchase price, including transaction fees	<u>\$ 54.7</u>		
<u>Allocation of purchase price:</u>			
Inventory	\$ 3.7	Estimated Selling Price Less Cost of Disposal and a Reasonable Selling Profit	N/A
Trademarks	27.3	Income Approach Discounted Cash Flow Method	Indefinite
Developed Technology	<u>23.7</u>	Income Approach Discounted Cash Flow Method	Indefinite
Total	<u>\$ 54.7</u>		
Brethine(as restated):			
Total purchase price, including transaction fees	<u>\$ 26.6</u>		
<u>Allocation of purchase price:</u>			
Trademarks-Existing	\$ 11.3	Income Approach Discounted Cash Flow Method	20 years
Trademarks-Reformulated	9.4	Income Approach Discounted Cash Flow Method	20 years
Developed Technology	<u>5.9</u>	Income Approach Discounted Cash Flow Method	20 years
Total	<u>\$ 26.6</u>		

<u>Identifiable Assets</u>	<u>Value (millions)</u>	<u>How Valued</u>	<u>Useful Life</u>
Darvon/Darvocet (as restated):			
Total purchase price, including transaction fees	<u>\$ 212.6</u>		
<u>Allocation of purchase price:</u>			
Inventory	\$ 1.7	Estimated Selling Price Less Cost of Disposal and a Reasonable Selling Profit	N/A
Trademarks-Existing	80.3	Income Approach Discounted Cash Flow Method	20 years
Trademarks-Reformulated	50.3	Income Approach Discounted Cash Flow Method	20 years
Developed Technology	<u>80.3</u>	Income Approach Discounted Cash Flow Method	20 years
Total	<u>\$ 212.6</u>		
Elan Pain Portfolio:			
Total purchase price, including transaction fees	<u>\$ 103.4</u>		
<u>Allocation of purchase price:</u>			
Inventory	\$ 5.1	Estimated Selling Price Less Cost of Disposal and a Reasonable Selling Profit	N/A
Trademarks	49.1	Income Approach Discounted Cash Flow Method	20 years
Developed Technology	<u>49.2</u>	Income Approach Discounted Cash Flow Method	20 years
Total	<u>\$ 103.4</u>		

3. Accounts Receivable, Net

The following table presents the components of accounts receivable:

	December 31,	
	2003	2002
	(In thousands)	
Trade	\$ 33,448	\$ 30,843
Related parties	144	292
Total accounts receivable	<u>33,592</u>	<u>31,135</u>
Allowance for doubtful accounts	(978)	(1,668)
Total accounts receivable, net	<u>\$ 32,614</u>	<u>\$ 29,467</u>

4. Inventories, Net

The following table presents the components of inventories:

	December 31,	
	2003	2002
	(In thousands)	
Finished goods (including consigned inventory of \$4,792 in 2003)	\$ 18,579	\$ 11,110
Work-in-process	1,865	1,866
Raw materials and supplies	5,007	4,749
Inventory reserves	(10,758)	(721)
Total inventories, net	<u>\$ 14,693</u>	<u>\$ 17,004</u>

5. Property and Equipment, Net

The following table presents the components of property and equipment:

	December 31,	
	2003	2002
	(In thousands)	
Land	\$ 2,784	\$ 2,688
Buildings and improvements	31,446	29,893
Machinery and equipment	69,593	62,814
Construction-in-progress	8,154	3,921
Cost of property and equipment	<u>111,977</u>	<u>99,316</u>
Less accumulated depreciation	(54,741)	(46,191)
Total property and equipment, net	<u>\$ 57,236</u>	<u>\$ 53,125</u>

Depreciation expense was approximately \$7.6 million, \$6.9 million and \$7.0 million for the years ended December 31, 2003, 2002 and 2001, respectively.

6. Debt and Credit Line

The following table presents the components of current maturities of long-term debt:

	December 31,	
	2003	2002
	(In thousands)	
Current maturities of long-term debt	\$ 4,000	\$ 5,921

The following table presents the components of long-term debt:

	December 31,	
	2003	2002
	(In thousands)	
U.S. bank term loan	\$ 156,000	\$ 50,000
U.S. revolving credit facility	8,000	47,500
11% senior subordinated notes due 2010, net of original issue discount	174,106	173,963
Interest rate swap monetization deferred income	12,189	10,486
Fair value of interest rate swap	(7,451)	1,871
Less current maturities of long-term debt	(4,000)	(5,921)
Total long-term debt due after one year	\$ 338,844	\$ 277,899

In March 2002, the Company entered into a \$175 million senior secured credit facility consisting of a \$75.0 million five-year revolving credit facility and a \$100 million five-year term loan facility. The term loan facility amortized over the full five-year term. The senior facilities were subsequently reduced due to early repayments made under the term loan facility. In December 2003, the remaining term loan facility of \$40 million was repaid and a new term loan facility was entered into. As part of this transaction, the Company recorded a \$1.5 million loss for the early extinguishment of debt related to the write-off of financing fees associated with the original term loan. The December 2003 term loan was a \$160 million facility which amortized over a six-year term. The net proceeds from this facility were used to fund the acquisition of the New Pain Products, as described in Note 2. In December 2003, the revolving credit facility was amended and increased to \$85 million, which was subsequently increased to \$100 million in January 2004. At December 31, 2003, the Company had unused availability under the revolving credit facility of \$77.0 million. The availability of borrowings under the revolving credit facility was not limited by a borrowing base. The term loan and revolving credit facilities provide for variable interest rates based on LIBOR or an alternate base rate, at the Company's option. On December 31, 2003, 30-day LIBOR was 1.12%. Such facilities are guaranteed by all domestic subsidiaries and secured by a security interest on substantially all domestic assets, all of the stock of domestic subsidiaries and 65% of the stock of material foreign subsidiaries. These senior credit

facilities require the payment of certain commitment fees based on the unused portion of the revolving credit facility and may be prepaid at any time without a premium.

Also in March 2002, the Company issued \$175 million of senior subordinated notes due April 1, 2010. The proceeds from the issuance of these notes were \$173.9 million, which was net of the original issue discount. This discount will be charged to interest expense over the term of the notes. These notes have a fixed interest rate of 11% per annum and are guaranteed on a subordinated basis by all existing domestic subsidiaries and all future domestic subsidiaries that are owned 80% or more by the Company. The notes are not secured. Prior to the third anniversary of the date of issuance of the notes, up to 35% of the notes are redeemable with the proceeds of qualified sales of equity at 111% of par value. On or after the fourth anniversary of the date of issuance of the notes, all or any portion of the notes are redeemable at declining premiums to par value, beginning at 105.5%.

Concurrent with the issuance of the senior subordinated notes, the Company entered into an interest rate hedging agreement to effectively convert interest expense on a portion of the senior subordinated notes for the term of the notes from an 11% fixed annual rate to a floating annual rate equal to 6-month LIBOR plus a base rate. On February 27, 2003, and again on June 23, 2003, the Company sold the then outstanding interest rate hedging agreement for \$2.3 million and \$3.7 million, respectively, and replaced it with a similar interest rate hedging agreement. The amounts received, less the interest benefits earned through the dates of sale, have been recorded as premiums to the carrying amount of the notes and are being amortized into interest income over their remaining life. At December 31, 2003, the Company had an interest rate hedging agreement in place covering \$150 million of the notes, at a rate of 6-month LIBOR plus 7.41%. On December 31, 2003, 6-month LIBOR was 1.22%, giving the Company an estimated all-in rate of 8.63%. The terms of the interest rate hedging agreements, other than the base rate, were identical and were perfectly matched with the terms of the related hedged instrument. On February 27, 2004, 6-month LIBOR was 1.17%.

Under the terms of the senior secured credit facility and the senior subordinated notes, the Company is required to comply with various covenants including, but not limited to, those pertaining to maintenance of certain financial ratios and incurring additional indebtedness. The Company was not in compliance with the covenants at December 31, 2003, see Note 1 for further discussion.

Scheduled maturities of long-term debt as of December 31, 2003, were as follows (in thousands):

2004	\$ 4,000
2005	16,000
2006	24,000
2007 (including the revolving credit facility)	40,000
2008	40,000
2009	40,000
2010	175,000
Total	<u>\$ 339,000</u>

As a result of aaiPharma's failure to timely file the Company's annual report on Form 10-K for the year ended December 31, 2003, among other matters, aaiPharma was in default of these term loan and revolving credit facilities. On April 23, 2004, aaiPharma refinanced these facilities with a portion of the proceeds from the M.V.I. sale and with \$140 million of senior credit facilities with a syndicate of lenders, Silver Point Finance LLC ("Silver Point") as collateral agent, and Bank of America, N.A., as administrative agent. The Company's

new senior credit facilities consist of a two-year, \$125 million senior secured term loan facility (which was fully drawn at closing) and a two-year, \$15 million senior secured revolving credit facility, of which the entire amount was available for borrowing at closing. The outstanding loans under the Company's new senior credit facilities are payable in full on the two-year anniversary date of the closing of the facilities. The Company's new senior credit facilities are secured by a security interest on substantially all domestic assets, all of the stock of domestic subsidiaries and 65% of the stock of material foreign subsidiaries. Subject to exceptions set forth in the definitive documentation, loans under the Company's new senior credit facilities are also required to be prepaid with a negotiated percentage of:

- excess cash flow, as defined;
- non-ordinary course assets sales;
- net proceeds from the sale of subordinated indebtedness;
- net proceeds from the issuance of equity issuances; and
- extraordinary receipts, as defined.

Optional reductions in revolving credit commitments and optional prepayments of term loans are subject to a prepayment fee equal to 3% for the first 9 months of the term of the facilities, 1.5% for the subsequent 9 months of such term, and 0.75% for the next 3 months of such term (with no prepayment penalty payable for the last 3 months of the term). Outstanding loans under the facilities bear interest at a rate per annum equal to a defined LIBOR rate (with a floor of 2%), plus 6.25%, or a defined reference rate (with a floor of 4%), plus 5.25%, in each case payable monthly in arrears. An additional 1% per annum unused line fee is payable on unused revolving credit commitments, payable quarterly in arrears.

The proceeds of the loans were used, together with the net cash proceeds from the sale of the M.V.I. and Aquasol product lines, to (i) fund payment of termination obligations with respect to the Company's interest rate hedging agreement (discussed below), (ii) refinance the Company's then-existing senior credit facilities, (iii) fund the April 2004 interest payment due on the Company's 11% senior subordinated notes due 2010, (iv) provide for ongoing working capital and general corporate needs, and (v) pay for fees, costs and expenses in connection with the new senior credit facilities and other corporate transactions.

The Company's new senior credit facilities include customary representations and warranties and customary affirmative and negative covenants, including limitations on liens, indebtedness, fundamental transactions, dispositions of assets, changes in the nature of the Company's business, investments, acquisitions, capital and operating leases, capital expenditures, dividends, redemptions or other acquisitions of capital stock, redemptions or prepayments of other debt, transactions with affiliates, issuances of capital stock, modifications of indebtedness, organizational documents and other agreements, and retention of excess cash. The facilities also provided for financial covenants, including a minimum fixed charge ratio, a maximum total debt to trailing twelve-month EBITDA ratio, and a covenant requiring a certain level of cash or revolver availability. The Company's new senior credit facilities include a covenant requiring the Company to file with the Securities and Exchange Commission by September 30, 2004 the Company's annual report on Form 10-K for the year ended December 31, 2003 and other periodic reports then required to be filed under the Securities Exchange Act of 1934. Events of default under the facilities include, among others, nonpayment of principal, interest or fees, violations of covenants, inaccuracy of representations and warranties, a cross-default to the Company's 11% senior subordinated notes due 2010 and other material indebtedness, bankruptcy events, and a change in control.

On March 31, 2004, the lenders under the Company's then-existing credit agreement, which was then in default as described above, exercised their right to block the Company from making the interest payment due on April 1, 2004 to holders of the Company's senior subordinated notes. Accordingly, aaiPharma did not make that interest payment on April 1, 2004. In addition, the Company's failure to timely file the Company's annual report on Form 10-K for the year ended December 31, 2003 constituted a default under the indenture governing the senior subordinated notes.

On April 20, 2004, aaiPharma completed a solicitation seeking the consent from holders of the Company's senior subordinated notes to approve a refinancing or replacement of the Company's then-existing credit facilities with the Company's new senior credit facilities and certain amendments to, and waivers under, the indenture governing the senior subordinated notes to, among other things:

- grant a lien to secure the Company's obligations under the senior subordinated notes, which lien is junior to the liens securing the Company's new senior credit facilities but covers the same collateral;
- increase the interest rate of the senior subordinated from 11% per annum to 11.5% per annum effective April 1, 2004;
- suspend the Company's obligation under the indenture to file periodic reports with the SEC until the earlier of the date that the Company's annual report on Form 10-K for the year ended December 31, 2003 is filed with the SEC or September 30, 2004 and suspend the Company's obligation to furnish annual written statements of the Company's accountants until the fifth day after the earlier of the date that the Company's annual report on Form 10-K for the year ended December 31, 2003 is filed with the SEC and September 30, 2004;
- further limit the Company's ability to grant liens to secure certain obligations unless the liens are subordinate to the liens securing the senior subordinated notes or are otherwise permitted under the indenture; and
- limit the Company's ability to incur up to \$10 million of indebtedness, and to grant liens to secure that amount of indebtedness, not otherwise specifically permitted by the indenture, until the Company's annual report on Form 10-K for the year ended December 31, 2003 is filed with the SEC or unless the indebtedness is incurred to fund an interest payment with respect to the senior subordinated notes.

Following the completion of a consent solicitation, aaiPharma entered into a supplemental indenture to affect these amendments and waivers and made the interest payments that had been due on April 1, 2004, together with default interest.

The Company made interest payments on the senior subordinated notes of \$9.6 million in October 2003 and \$9.7 million in April 2004. The April 2004 interest payment was offset by approximately \$1.7 million received under the Company's interest rate hedging agreement, described above.

As a condition to establishing the Company's new senior credit facilities, aaiPharma terminated the interest rate hedging agreement in April 2004. The Company's termination obligations under the interest rate hedging agreement were approximately \$9.4 million, which amount was paid upon termination of that agreement.

7. Stockholders' Equity

The authorized capital stock of the Company at December 31, 2003 and 2002 was 100 million shares of voting common stock, \$0.001 par value per share, and 5 million shares of preferred stock, \$0.001 par value per share. The preferred stock is issuable in one or more series by the Company's Board of Directors without further stockholder approval. No preferred stock was outstanding at December 31, 2003 or 2002. The Company has reserved 1.0 million shares of common stock for issuance under the stock option plans at December 31, 2003.

Stock Option and Award Plans

The Company has five stock option plans: the 2000 Stock Option Plan for Non-Employee Directors (the "2000 Plan"), the 1997 Stock Option Plan (the "1997 Plan"), the 1996 Stock Option Plan (the "1996 Plan"), the 1995 Stock Option Plan (the "1995 Plan") and the 1996 Incentive and Non-Qualified Stock Option Plan (the "MTRA Plan"). Under the 1995 Plan, the Board of Directors initially could grant options to purchase up to 363,807 shares of common stock. However, the Company has no obligation to issue the shares upon exercise of such options until it has purchased an equal number of shares from certain existing stockholders. Under the 2000 Plan, the 1997 Plan and the 1996 Plan, the Board of Directors initially could grant options to purchase up to 615,000, 3,966,000 and 743,441, respectively, of newly issued shares of common stock. The Board of Directors reserved 776,250 shares to cover the exercise of the options under the MTRA Plan. The plans require that the exercise price of options cannot be less than either 100% (2000 Plan, 1997 Plan and MTRA Plan) or 75% (1996 and 1995 Plans) of the estimated fair market value of the Company's shares of common stock on the date of grant. As of December 31, 2003, the Company had granted 1,160,251 options to certain executives that cliff vest after seven years. These options, however, have an accelerated vesting provision where granted options will vest in the following proportions if the Company's share closing price equals or exceeds the following share price for seven consecutive days: 25%, \$22.67; 50%, \$34.00; 75%, \$45.33; and 100%, \$55.67.

The combined activity from all plans is presented in the following table:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2000	3,561,753	\$ 6.78
Granted	857,748	10.61
Exercised	(594,024)	6.43
Forfeited	(329,499)	8.11
Outstanding, December 31, 2001	<u>3,495,978</u>	7.65
Granted	3,387,798	14.24
Exercised	(512,423)	6.33
Forfeited	(962,380)	14.13
Outstanding, December 31, 2002	<u>5,408,973</u>	10.79
Granted	1,884,755	15.37
Exercised	(618,723)	8.36
Forfeited	(247,401)	12.83
Outstanding, December 31, 2003	<u><u>6,427,604</u></u>	12.28

Information regarding stock options outstanding and options exercisable at December 31, 2003 is summarized in the table below:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares Outstanding	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Shares Exercisable	Weighted Average Exercise Price
\$4.58 - \$9.75	1,757,050	5.93	\$ 6.97	1,612,844	\$ 6.80
\$9.76 - \$12.65	1,755,625	8.43	11.41	543,721	11.38
\$12.73 - \$14.96	1,955,019	8.74	14.65	518,667	14.66
\$15.11 - \$24.56	959,910	9.24	18.79	114,816	19.45
\$4.58 - \$24.56	6,427,604	7.96	12.28	2,790,048	9.67

At December 31, 2003, 2002 and 2001, exercisable options representing 2.8 million, 1.8 million and 1.4 million shares, respectively, were outstanding.

8. Related Party Transactions

Endeavor Pharmaceuticals, Inc.

In 1994, aaiPharma organized Endeavor Pharmaceuticals, Inc. ("Endeavor") with several investors to fund the development of hormone pharmaceutical products, initially focusing on several generic hormone products already under development by the Company. The Company also agreed to permit Endeavor, under certain circumstances, the first right to purchase additional proprietary hormone pharmaceutical products developed by aaiPharma. aaiPharma obtained a 47% equity interest in Endeavor through the contribution of its accumulated product research and development and technical know-how. The other investors contributed cash in exchange for their interests which, for all investors, was in the form of convertible preferred stock. Based on subsequent investments by other investors, the Company's interest, assuming conversion, had been reduced to approximately 10% of the fully diluted common equity of Endeavor. Subsequent to the reduction in ownership percentage and its reduced influence over the Endeavor operations, the Company ceased accounting for this as an equity method investment and began to account for it under the cost method. Endeavor has accumulated significant losses since inception and this investment had been recorded at zero value since 1995. In the fourth quarter of 2003, Endeavor sold substantially all of its assets to a third party. As part of this transaction, the Company recorded a pretax gain of \$1.8 million for the sale of its investment in Endeavor. This gain is included in other income on the consolidated statements of operations. As of December 31, 2003, the Company no longer had any investment in Endeavor.

The Company had net sales to Endeavor of approximately \$0.6 million, \$1.1 million and \$0.2 million for the years ended December 31, 2003, 2002 and 2001, respectively. At December 31, 2003, the Company had no related accounts receivable and at December 31, 2002, the Company had \$0.3 million in related accounts receivable.

Aesgen, Inc.

Aesgen, Inc. ("Aesgen") was formally organized with an affiliate of the Mayo Clinic and MOVA Pharmaceutical Corporation and funded in 1995 through the issuance of approximately \$11 million of nonconvertible, nonvoting, mandatorily redeemable, preferred stock. The Company made a cash investment of \$1.6 million in such preferred stock, which is carried at cost, and is included in other noncurrent assets on the consolidated balance sheets. In January 2001, the terms of the preferred stock owned by the Company were amended to make that class of stock convertible into Aesgen common stock.

In October 2001, the Company entered into a Service Agreement and a Subscription Agreement with Aesgen, whereby the Company has agreed to perform certain clinical work for Aesgen and to receive Aesgen preferred stock in lieu of cash for the services performed. The Company has subscribed to \$1.1 million of preferred stock, and will receive up to 10,829 shares of such stock, in lieu of cash for the related shares. Through December 31, 2003, the Company has performed services under the agreement of \$580,000. At December 31, 2003, the Company held 10% of Aesgen's fully diluted common stock. The Company does not anticipate performing any additional services for Aesgen under this agreement.

In February 2002, the Company purchased a proprietary product from Aesgen for payments of \$1.0 million in cash and additional contingent milestone payments of up to \$1.5 million. In 2003, the prerequisite for payment of an additional \$500,000 of such contingent milestones occurred and such payment was made to Aesgen, while the prerequisites for payment of the remaining \$1.0 million were not met and no further payment of this amount is owed by the Company. Under this agreement, the Company is obligated to pay royalty payments for the eight-year period following the first commercial sale of the product. In 2003, the Company expensed royalties related to this agreement of \$0.6 million. Of this amount, none was payable at December 31, 2003.

In 1996, the Company sold to Aesgen marketing rights to a product under development by the Company. Under the agreement, Aesgen paid a license fee and would have paid additional royalties upon marketing the product. aaiPharma had the right, under its development agreement with Aesgen, to provide certain product development and support services to Aesgen with respect to some generic drugs currently being developed by Aesgen, provided that aaiPharma's fees for such services were comparable to those of a competitor. In addition, under such development agreement, the Company had agreed not to develop, for its own account or any other person, a formulation of any of the generic products currently under development for Aesgen and any additional drugs that aaiPharma agrees to develop in the future for Aesgen.

aaiPharma recognized net revenues of zero, \$494,000 and \$86,000 from Aesgen for the years ended December 31, 2003, 2002 and 2001 respectively. The Company had no related accounts receivable from Aesgen or work-in-progress at December 31, 2003 or 2002.

Cetan Technologies, Inc.

The Company used Cetan Technologies, Inc. (Cetan), to provide scanning and indexing services required as part of aaiPharma's regulatory compliance and record retention policies. Cetan's principal stockholders include Dr. Frederick Sancilio and Mr. James Waters, both directors of aaiPharma. The Company engaged Cetan to perform these services since 1996 and compensated Cetan pursuant to written agreements for the services. Cetan also provided computer validation services to aaiPharma, which were required for compliance with regulatory

requirements. Total payments for scanning and validation services provided to aaiPharma by Cetan were zero, \$7,000 and \$4,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

9. Income Taxes

The following table presents the components for the (benefit from) provision for income taxes:

	Years Ended December 31,		
	2003	2002 (as restated)	2001
	(In thousands)		
(Loss) income before income taxes:			
United States	\$ (38,600)	\$ 21,758	\$ 9,096
Non-U.S.	1,395	(98)	43
(Loss) income before taxes	<u>\$ (37,205)</u>	<u>\$ 21,660</u>	<u>\$ 9,139</u>
(Benefit from) provision for income taxes:			
Current:			
Federal	\$ 14,824	\$ 1,842	\$ 1,654
State	67	219	1,397
Non-U.S.	113	355	-
Total current taxes	<u>15,004</u>	<u>2,416</u>	<u>3,051</u>
Deferred:			
Federal	(18,398)	4,517	1,067
State	(1,108)	1,609	(919)
Total deferred taxes	<u>(19,506)</u>	<u>6,126</u>	<u>148</u>
(Benefit from) provision for income taxes	<u>\$ (4,502)</u>	<u>\$ 8,542</u>	<u>\$ 3,199</u>

The following table presents the reconciliation of the (benefit from) provision for income taxes to the amount computed by applying the U.S. federal statutory income tax rate:

	Years Ended December 31,		
	2003	2002 (as restated)	2001
	(In thousands)		
(Loss) income before income taxes	<u>\$ (37,205)</u>	<u>\$ 21,660</u>	<u>\$ 9,139</u>
Tax (benefit) expense using U.S. statutory income tax rate of 35% for 2003 and 2002, and 34% for 2001	\$ (13,022)	\$ 7,581	\$ 3,107
State income taxes, net	(1,972)	1,141	(11)
Permanent items, net	1,299	329	395
Non-U.S. operations, net	(1,542)	(194)	(53)
Tax credits	(450)	(677)	(368)
Change in deferred tax asset valuation allowance	11,185	362	129
(Benefit from) provision for income taxes	<u>\$ (4,502)</u>	<u>\$ 8,542</u>	<u>\$ 3,199</u>

Deferred income taxes arise from temporary differences between the tax bases of assets and liabilities and their reported amounts in the financial statements. Deferred taxes are included in prepaid and other current assets, other accrued liabilities and other long-term liabilities. The following table presents the Company's deferred tax assets and liabilities:

	December 31,	
	2003	2002
	(In thousands)	
Deferred tax assets, resulting from:		
Accrued liabilities	\$ 1,069	\$ 1,724
Accounts receivable	332	1,493
Deferred revenue	17,371	903
U.S. net operating loss carryforwards	359	1,811
Non-U.S. net operating losses	4,196	2,826
Accrued reserves and other	18,426	276
Total deferred tax assets	<u>41,753</u>	<u>9,033</u>
Deferred tax liabilities, resulting from:		
Amortization	(6,064)	(3,138)
Property and equipment	(4,555)	(5,453)
Total deferred tax liabilities	<u>(10,619)</u>	<u>(8,591)</u>
Valuation allowances on tax assets	<u>(14,196)</u>	<u>(3,011)</u>
Net deferred tax assets (liabilities)	<u>\$ 16,938</u>	<u>\$ (2,569)</u>

Valuation allowances have been provided for certain assets resulting from accumulated net operating losses from foreign entities and other deferred tax assets because FAS 109 requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion of the deferred tax asset will not be realized. As of December 31, 2003, the Company had no federal net operating losses and \$5 million of state net operating loss carryforwards, expiring in 2005.

Undistributed earnings of certain consolidated foreign subsidiaries at December 31, 2003, amounted to \$2.9 million. No provision for deferred U.S. income taxes has been made for these subsidiaries because aaiPharma intends to permanently reinvest such earnings in those foreign operations. If such earnings were not permanently reinvested, a deferred tax liability would have been required.

10. Employee Benefit Plan

The Company provides retirement benefits for all domestic aaiPharma employees with one year of service through a defined contribution plan qualified under section 401(k) of the Internal Revenue Code of 1986, as amended. Participants may elect to contribute a portion of their annual compensation, subject to limitations. The Company makes matching contributions in aaiPharma stock equal to 50% of a participant's contribution up to a certain amount. Additionally, the Company may make profit-sharing contributions at the discretion of the Board of Directors. The Company expensed \$1.1 million, \$1.0 million and \$0.8 million for the years ended December 31, 2003, 2002 and 2001, respectively, for this benefit plan, all related to the matching contributions.

11. Commitments and Contingencies

The Company leases land, buildings and equipment under renewable lease agreements classified as operating leases. Rent expense under these agreements for the years ended December 31, 2003, 2002 and 2001 was \$7.1 million, \$7.0 million and \$6.9 million, respectively. As of December 31, 2003, future minimum rentals due under non-cancelable operating lease agreements with initial terms of one year or more were: \$7.7 million--2004; \$6.6 million--2005; \$4.8 million--2006; \$4.6 million--2007; \$4.5 million--2008 and \$7.3 million--thereafter. As of December 31, 2003, future minimum rentals due under non-cancelable capital lease agreements with initial terms of one year or more were: \$0.3 million--2004; \$0.2 million--2005; \$0.2 million--2006; and zero--thereafter.

In 2003, the Company entered a three-year services agreement with Athlon Pharmaceuticals, Inc. ("Athlon") to provide sales support in designated territories throughout the United States for the Darvocet A500 product. As of December 31, 2003, future minimum payments due under this agreement were: \$14.4 million--2004; \$14.4 million--2005; \$10.8 million--2006; and zero--thereafter. The Company has commenced litigation against Athlon with respect to this agreement, and terminated this agreement, as described below. The Company also entered into a multi-year supply agreement for Darvocet A500 with a separate third party. As of December 31, 2003, the minimum guaranteed purchase requirement remaining under this agreement was \$12.9 million. The Company has amended this agreement to allow additional Company products to be manufactured under this supply agreement and for these products to be counted against the minimum purchase obligation, although the Company and this party have not yet agreed on the terms for manufacturing these additional products, including price.

In 1995, the Company entered into an employment agreement with Dr. Frederick D. Sancilio, which was most recently amended in 2003. The employment agreement renews automatically for successive two-year periods unless either party notifies the other party of an intention not to extend the term. Dr. Sancilio currently serves as aaiPharma's Executive Chairman of the Board, Chief Executive Officer and Chief Scientific Officer. The Board of Directors set Dr. Sancilio's annual salary at \$422,000 effective January 1, 2003, which has not yet been adjusted to reflect his resumption of responsibilities as Chief Executive Officer in March 2004. Pursuant to the employment agreement, Dr. Sancilio receives a bonus when aaiPharma receives certain regulatory approvals. This bonus is in the amount of \$250,000 for each new drug application and \$50,000 for each supplemental new drug application or abbreviated new drug application. Dr. Sancilio was awarded a bonus of \$100,000 in March 2003 upon regulatory approval and commercialization of two products. The employment agreement permits the Company to terminate Dr. Sancilio's employment at any time, with or without cause. However, if the Company terminates Dr. Sancilio's employment without cause or if Dr. Sancilio terminates his employment within 90 days after a "constructive discharge" (as defined in the agreement), Dr. Sancilio would be entitled to receive payments aggregating three times his then current annual salary. These payments would be made in monthly installments over two years, during which time Dr. Sancilio would continue to receive his medical and life insurance benefits.

The Company is party to lawsuits and administrative proceedings incidental to the normal course of its business. The Company is also party to, or named as a defendant in, purported class action lawsuits alleging violations of federal securities and ERISA laws.

On August 7, 2003 the Company received a letter from the staff of the Enforcement Division of the SEC (the "Enforcement Division") requesting voluntary production of certain documents. The Company responded to this letter on August 21, 2003 and supplemented its response on August 29, 2003.

Independent of the August 7, 2003 inquiry letter, on September 26, 2003, certain members of the Company's board and management voluntarily met with, and provided documents to, the staff of the Enforcement Division. As a follow-up to this September 26, 2003 meeting and as part of the inquiry initiated on August 7, 2003, on October 8, 2003, the Company received a further request from staff of the Enforcement Division for voluntary production of certain documents, to which the Company responded on October 30, 2003.

On January 14, 2004 and April 26, 2004, the Company received letters from the SEC's Division of Corporate Finance commenting on, asking questions about, and seeking additional disclosure with respect to certain of our periodic reports. The Company has responded to these letters.

In April 2004, in connection with an investigation conducted by the United States Attorneys Office for the Western District of North Carolina (the "U.S. Attorneys Office"), the Company received five federal grand jury subpoenas for document production and potential testimony related to, among other things, certain transactions regarding its 2002 and 2003 financial information, the terms, conditions of employment and compensation arrangements of certain of its senior management personnel, compensation and incentive arrangements for employees responsible for the sale of its Brethine, Darvocet, calcitriol, azathioprine and Darvon Compound products, quantities of the foregoing products in distribution channels, financial benefits with respect to specified corporate transactions to its senior management and others, certain loans obtained by it, extensions of credit, if any, by it to officers or directors, accounting for sales and returns of its foregoing products, its analysts' conference calls on financial results, internal and external investigations of pharmaceutical product sales activities, and related matters. The Company also been advised that the SEC has initiated an inquiry into at least the same issues investigated by the Special Committee. The U.S. Attorneys Office has advised that the Company may also receive a subpoena from the SEC.

The Company and the Special Committee have agreed to cooperate fully with the government investigations, and the Special Committee has agreed to share all results of its investigation with the SEC and the U.S. Attorneys Office. To that end, two meetings of outside counsel of the Company with attorneys for the U.S. Attorneys Office and the SEC have taken place and numerous documents as requested by these government agencies have been voluntarily produced. We are attempting to schedule a third meeting with the U.S. Attorneys Office and the SEC in July in order to provide additional information related to the Special Committee's investigation to these government agencies. The Company and the Special Committee intend to facilitate any interviews of employees or officers of the Company that may be requested by these government agencies.

The Department of Justice, SEC and other government agencies that are investigating or might commence an investigation of the Company could impose, based on a claim of fraud, material misstatements, violation of false claims law or otherwise, civil and/or criminal sanctions, including fines, penalties, and/or administrative remedies. If any government sanctions are imposed, which the Company cannot predict or reasonably estimate at this time, the Company's business, financial condition, results of operations or cash flows could be materially adversely affected. These matters have resulted, and are expected to continue to result, in a significant diversion of management's attention and resources and in significant professional fees.

On January 2, 2004, aaiPharma received separate letters from the Kentucky Office of Attorney General and the Florida Office of Attorney General advising that each was currently investigating allegations regarding the Company's pricing practices related to the Company's average manufacturer price and best price calculations that are used by the government to set Medicaid reimbursement rates. Neither letter requested that aaiPharma provide any information, and each letter merely requested that aaiPharma retain all documents with respect to these calculations pursuant to a newly adopted federal regulation that would have permitted the destruction of

these documents three years after the applicable prices were reported, except to the extent aaiPharma was aware of an ongoing investigation. It is the Company's understanding that many other pharmaceutical companies received similar letters at that time from attorneys general in a number of states and that such letters may have been in response to the new federal regulation that would have otherwise allowed the destruction of documents reflecting these pricing calculations. A number of attorneys general, including the Florida and Kentucky attorneys general, petitioned the U.S. Secretary of Health and Human Services to withdraw the new regulation. aaiPharma is not aware of any further developments in these investigations.

The Company and certain of its officers have been named as defendants in purported shareholder class action lawsuits alleging violations of federal securities laws. These lawsuits were filed beginning in February 2004 and are pending in the U.S. District Court for the Eastern District of North Carolina. These lawsuits assert claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of the Company's common stock during the period from January 31, 2002 through and including March 1, 2004 (the "Class Period"). The complaints allege generally that the defendants knowingly or recklessly made false or misleading statements during the Class Period concerning the Company's financial condition and that the Company's financial statements did not present its true financial condition and were not prepared in accordance with generally accepted accounting principles. The complaints seek certification as a class action, unspecified compensatory damages, attorneys' fees and costs, and other relief. By order dated April 16, 2004, the district court consolidated the securities lawsuits into one consolidated action. The Company expects that the plaintiffs will file a consolidated, amended complaint later in 2004, to which the Company will respond in lieu of responding to the individual complaints.

In addition, the Company, one of its former officers, certain of its employees and others have been named in a purported class action brought by an aaiPharma retirement plan participant and beneficiary asserting claims under the Employee Retirement Income Security Act of 1974, as amended ("ERISA") on behalf of a class of all persons who are or were participants or beneficiaries of the aaiPharma Inc. Retirement and Savings Plan (the "Plan") during the period from April 24, 2002 to March 31, 2004. The complaint alleges generally that the defendants breached fiduciary duties owed under ERISA with respect to the investment of Plan assets in aaiPharma stock by misleading participants and beneficiaries of the Plan regarding the Company's earnings, prospects, and business condition. The complaint seeks certification as a class action, unspecified compensatory damages, attorneys' fees and costs, and other relief.

These securities and ERISA lawsuits are at an early stage. By, and subject to, the terms of our bylaws, the Company has certain obligations to indemnify the officers of the Company and others who have been named as defendants in these lawsuits. The Company has purchased directors and officers liability insurance ("D&O insurance") that may provide coverage for some or all of these lawsuits and governmental investigations. There is a risk, however, that some or all of the claims or expenses will not be covered by such policies; or that, even if covered, the Company's ultimate liability will exceed the available insurance. Although the Company intends to vigorously pursue all defenses available in these lawsuits, an adverse determination in these lawsuits or an inability to obtain payment under the Company's D&O insurance policies for litigation and indemnification costs and any damages ultimately borne by the Company as a result of these lawsuits and investigations could have a material adverse effect on the Company's business, financial condition, results of operations or cash flows.

On April 15, 2004, the Company filed a lawsuit against Athlon seeking a declaratory judgment that the Company was entitled to terminate the Service Agreement (the "Athlon Service Agreement") dated July 16, 2003, as amended, between aaiPharma and Athlon as well as damages and injunctive relief for material

breaches of the Athlon Service Agreement by Athlon. The Athlon Service Agreement incorporated the terms and conditions pursuant to which representatives of Athlon would promote the sale of our Darvocet A500 product to physicians. The Company initially paid Athlon \$3,350,000 to build its sales force to promote the sale of our Darvocet A500, and the terms of the Athlon Service Agreement would require the Company to pay Athlon an additional \$1,200,000 each month for such services for the contract period of 36 months, commencing in October 2003, subject to Athlon's compliance with certain representations, warranties and covenants, some of which are described below.

The lawsuit asserts that Athlon has materially breached the Athlon Service Agreement in several ways, including failure to: (i) provide the required number of sales representatives during our launch of Darvocet A500 commencing in October 2003, (ii) use its best efforts to promote Darvocet A500 at the targeted levels of first and second pharmaceutical details to physicians, (iii) perform the services to the best of its ability, as contractually required; and (iv) require its sales representatives to perform the contracted services, as required, in a professional manner consistent with industry standards and in conformance with that level of care and skill ordinarily exercised by professional contract sales organizations in similar circumstances. The lawsuit also asserts that Athlon breached its representation and warranty that it would perform, and would require its sales representatives to perform, the contracted services in substantially the same manner that it would promote Athlon's own products.

Athlon has asserted several counterclaims, including breach of an implied covenant of good faith in fair dealing and anticipatory breach of the contract. The Company has filed a reply denying these allegations.

On June 4, 2004, the Company sent a notice of termination of the Athlon Service Agreement to Athlon. The Company also informed Athlon of its intent to amend the lawsuit to assert the defense of fraud in the inducement in the formation of the agreement on the part of Athlon and other claims.

The Company intends to prosecute its claims, and defend against the counterclaims made by Athlon in connection with the referenced lawsuit or related litigation, to the full extent permitted by law.

The Company is a party to a number of legal actions with generic drug companies. The Company is involved in four lawsuits centered on its omeprazole-related patents, including one lawsuit brought by the Company against an alleged infringer of the Company's patents and three lawsuits which were brought by third parties against the Company and are currently essentially inactive. Omeprazole is the active ingredient found in Prilosec, a drug sold by AstraZeneca.

Two omeprazole-related cases have been filed against the company by Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. in the U.S. District Court for the Southern District of New York in July 2001 and November 2001. The plaintiffs in these cases have challenged the validity of five patents that the Company has obtained relating to omeprazole and are seeking a declaratory judgment that their generic form of Prilosec does not infringe these patents. Additionally, they have alleged misappropriation of trade secrets, tortious interference, unfair competition and violations of the North Carolina Unfair Trade Practice Act.

The third case involving the Company's omeprazole patents was brought in August 2001 by Andrx Pharmaceuticals, Inc. in the U.S. District Court for the Southern District of New York. Andrx has challenged the validity of three of the Company's omeprazole patents and has also sought a declaratory judgment that its generic omeprazole product does not infringe these patents. Furthermore, Andrx claims violations of federal

and state antitrust laws with respect to the licensing of these omeprazole patents and has sought injunctive relief and unspecified treble damages.

The fourth case involving the omeprazole patents was brought in December 2002, and subsequently amended, by the Company against Kremers Urban Development Co., Schwarz Pharma Inc. and Schwarz Pharma AG (collectively, "KUDCO") in the U.S. District Court for the Southern District of New York. KUDCO has a generic omeprazole product with final FDA marketing approval, was found not to infringe the AstraZeneca patents in the separate AstraZeneca patent litigation, and is currently selling its generic substitute for Prilosec in the U.S. marketplace. KUDCO has filed its answer to the complaint, denying the Company's claims, asserting various affirmative defenses to the claims, and asserting counterclaims of patent invalidity, product non-infringement and antitrust violations under federal and state antitrust laws. KUDCO is also contesting the personal jurisdiction of the court over all of the defendants in this lawsuit other than Kremers Urban Development Co. and Schwarz Pharma Inc. Motions on the jurisdictional issues are pending before the court. The Company has denied the substantive allegations made by KUDCO in its counterclaims. The Company has previously indicated to KUDCO a willingness to grant a license under its omeprazole patents for an appropriate royalty. In the absence of a license, the Company intends to vigorously prosecute the case, defend its patent rights and defend against the foregoing defenses and counterclaims asserted by KUDCO.

The Company cannot predict the outcomes of these lawsuits. Future adverse findings in the above described lawsuits could have a material adverse effect on its consolidated financial condition, results of operations or cash flows.

12. Financial Information by Business Segment and Geographic Area

The Company operates in three business segments consisting of a product sales business, primarily comprised of the pharmaceuticals division, a product development business, primarily the research and development business unit, and a development services business, primarily the AAI Development Services business unit. The product sales business provides for the sales of the Company's pharmaceutical product lines and for the commercial manufacturing of small quantity products outsourced by other pharmaceutical companies. In the product development segment, the Company internally develops drugs and technologies for future sales by the product sales business or with the objective of licensing marketing rights to third parties in exchange for license fees and royalties. The core services provided by the development services business on a fee-for-service basis to pharmaceutical and biotechnology industries worldwide include comprehensive formulation, testing and manufacturing expertise, in addition to the ability to take investigational products into and through human clinical trials. The majority of the Company's non-U.S. operations are located in Germany.

Corporate income (loss) from operations includes general corporate overhead costs and, in fiscal 2001, goodwill amortization, which are not directly attributable to a business segment. Financial data by segment and geographic region are as follows:

	Years Ended December 31,		
	2003	2002 (as restated)	2001
	(in thousands)		
Net revenues:			
Product sales	\$ 122,021	\$ 128,462	\$ 27,448

Product development	16,468	19,610	20,426
Development services	86,488	82,438	93,199
	<u>\$ 224,977</u>	<u>\$ 230,510</u>	<u>\$ 141,073</u>

United States	\$ 204,660	\$ 228,827	\$ 129,464
Germany	20,623	15,520	15,442
Other	1,665	962	916
Less intercompany	(1,971)	(14,799)	(4,749)
	<u>\$ 224,977</u>	<u>\$ 230,510</u>	<u>\$ 141,073</u>

Income (loss) from operations:

Product sales	\$ 2,483	\$ 66,880	\$ 7,691
Product development	16,468	19,610	20,426
Development services	979	556	8,920
	<u>19,930</u>	<u>87,046</u>	<u>37,037</u>
Research and development expense	(22,205)	(21,279)	(10,851)
Corporate	(19,038)	(17,149)	(12,957)
	<u>\$ (21,313)</u>	<u>\$ 48,618</u>	<u>\$ 13,229</u>

United States	\$ (22,420)	\$ 49,020	\$ 13,095
Germany	1,150	(58)	440
Other	(43)	(344)	(306)
	<u>\$ (21,313)</u>	<u>\$ 48,618</u>	<u>\$ 13,229</u>

Depreciation and amortization:

Product sales	\$ 13,161	\$ 9,945	\$ 552
Development services	4,515	3,903	4,503
Research and development expense	416	425	369
Corporate	2,154	2,122	2,331
	<u>\$ 20,246</u>	<u>\$ 16,395</u>	<u>\$ 7,755</u>

Total assets:

Product sales	\$ 424,452	\$ 340,773	\$ 105,541
Product development	13,062	6,024	7,832
Development services	55,791	49,952	55,555
Corporate	41,292	36,753	27,358
	<u>\$ 534,597</u>	<u>\$ 433,502</u>	<u>\$ 196,286</u>

United States	\$ 504,575	\$ 411,174	\$ 176,518
Germany	28,459	21,167	18,794

Other	<u>1,563</u>	<u>1,161</u>	<u>974</u>
	<u>\$ 534,597</u>	<u>\$ 433,502</u>	<u>\$ 196,286</u>

Goodwill, net:

Development services	<u>\$ 13,361</u>	<u>\$ 11,378</u>	<u>\$ 9,663</u>
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13. Financial Results by Quarter (Unaudited)

	Quarter							
	First		Second		Third		Fourth	
	(In thousands, except per share amounts)							
	As Previously Reported	As Restated	As Previously Reported	As Restated	As Previously Reported	As Restated		
2003								
Net revenues	\$ 64,030	\$ 48,987	\$ 70,751	\$ 66,096	\$ 71,012	\$ 39,700	\$ 70,194	
(Loss) income from operations	17,175	1,575	17,384	10,580	19,104	(10,337)	(23,131)	
Net income (loss)	7,156	(2,468)	7,988	3,492	8,928	(9,392)	(24,335)	
Basic earnings (loss) per share	\$ 0.26	\$ (0.09)	\$ 0.29	\$ 0.13	\$ 0.32	\$ (0.34)	\$ (0.87)	
Diluted earnings (loss) per share	0.25	(0.09)	0.28	0.12	0.31	(0.34)	(0.87)	

	Quarter							
	First		Second		Third		Fourth	
	(In thousands, except per share amounts)							
	As Previously Reported	As Restated	As Previously Reported	As Restated	As Previously Reported	As Restated	As Previously Reported	As Restated
2002								
Net revenues	\$ 45,620	\$ 45,620	\$ 61,447	\$ 61,447	\$ 61,209	\$ 61,209	\$ 62,234	\$ 62,234
Income from operations	5,059	4,853	16,328	14,123	17,041	14,386	17,014	14,806
Net income (loss)	(3,250)	(3,376)	6,104	4,749	7,104	5,748	7,356	5,997
Basic earnings (loss) per share	\$ (0.12)	\$ (0.12)	\$ 0.22	\$ 0.17	\$ 0.26	\$ 0.21	\$ 0.27	\$ 0.22
Diluted earnings (loss) per share	(0.12)	(0.12)	0.21	0.17	0.25	0.20	0.26	0.21

14. Financial Information for Subsidiary Guarantors and Non-Guarantors

In the first quarter of 2002, the Company issued senior subordinated notes which are guaranteed by certain of the Company's subsidiaries.

The following presents condensed consolidating financial information for the Company, segregating: (1) aaiPharma Inc., which issued the notes (the "Issuer"); (2) the domestic subsidiaries, which guarantee the notes (the "Guarantor Subsidiaries"); and (3) all other subsidiaries (the "Non-Guarantor Subsidiaries"). The Guarantor Subsidiaries are wholly-owned direct subsidiaries of the Company and their guarantees are full, unconditional and joint and several. Wholly-owned subsidiaries are presented on the equity basis of accounting. Certain reclassifications have been made to conform all of the financial information to the financial presentation on a consolidated basis. The principal adjusting entries eliminate investments in subsidiaries and intercompany balances and transactions.

The following information presents consolidating statements of operations, balance sheets and cash flows for the periods and as of the dates indicated:

aaiPharma Inc.
CONSOLIDATING STATEMENT OF OPERATIONS
(In thousands)

	Year Ended December 31, 2003				
	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Net revenues	\$ 44,834	\$ 159,826	\$ 22,288	\$ (1,971)	\$ 224,977
Equity earnings from subsidiaries	(16,949)	-	-	16,949	-
Total revenues	27,885	159,826	22,288	14,978	224,977
Operating costs and expenses:					
Direct costs (excluding depreciation and royalty expense)	27,549	75,090	13,680	(1,482)	114,837
Selling	6,465	30,861	2,208	-	39,534
General and administrative	28,595	7,746	4,122	-	40,463
Research and development	-	21,777	-	11	21,788
Depreciation	5,466	1,334	1,173	-	7,973
Royalty expense	-	1,095	-	-	1,095
Intangible asset impairment	-	20,600	-	-	20,600
	68,075	158,503	21,183	(1,471)	246,290
(Loss) income from operations	(40,190)	1,323	1,105	16,449	(21,313)
Other income (expense):					
Interest, net	(1,654)	(19,598)	174	-	(21,078)
Net intercompany interest	(2,027)	2,199	(172)	-	-
Other	6,636	(1,468)	18	-	5,186
	2,955	(18,867)	20	-	(15,892)
(Loss) income before income taxes	(37,235)	(17,544)	1,125	16,449	(37,205)
(Benefit from) provision for income taxes	(4,532)	30	-	-	(4,502)
Net (loss) income	\$ (32,703)	\$ (17,574)	\$ 1,125	\$ 16,449	(32,703)

aaiPharma Inc.
RESTATED CONSOLIDATING STATEMENT OF OPERATIONS
(In thousands)

	Year Ended December 31, 2002				
	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Net revenues	\$ 59,973	\$ 168,854	\$ 16,483	\$ (14,800)	\$ 230,510
Equity earnings from subsidiaries	48,465	-	-	(48,465)	-
Total revenues	<u>108,438</u>	<u>168,854</u>	<u>16,483</u>	<u>(63,265)</u>	<u>230,510</u>
Operating costs and expenses:					
Direct costs (excluding depreciation)	38,536	56,212	10,438	(14,489)	90,697
Selling	6,348	14,954	1,775	-	23,077
General and administrative	27,532	8,900	3,677	-	40,109
Research and development	732	20,121	-	-	20,853
Depreciation	5,153	1,005	998	-	7,156
	<u>78,301</u>	<u>101,192</u>	<u>16,888</u>	<u>(14,489)</u>	<u>181,892</u>
Income (loss) from operations	30,137	67,662	(405)	(48,776)	48,618
Other (expense) income					
Interest, net	(1,774)	(17,602)	10	-	(19,366)
Net intercompany interest	(2,292)	2,494	(202)	-	-
Other	(4,215)	(3,678)	301	-	(7,592)
	<u>(8,281)</u>	<u>(18,786)</u>	<u>109</u>	<u>-</u>	<u>(26,958)</u>
Income (loss) before income taxes	21,856	48,876	(296)	(48,776)	21,660
Provision for income taxes	8,738	-	(196)	-	8,542
Net income (loss)	<u>\$ 13,118</u>	<u>\$ 48,876</u>	<u>\$ (100)</u>	<u>\$ (48,776)</u>	<u>\$ 13,118</u>

aaiPharma Inc.
CONSOLIDATING STATEMENT OF OPERATIONS
(In thousands)

	Year Ended December 31, 2001				
	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Net revenues	\$ 57,842	\$ 71,622	\$ 16,357	\$ (4,748)	\$ 141,073
Equity earnings from subsidiaries	22,419	-	-	(22,419)	-
Total revenues	80,261	71,622	16,357	(27,167)	141,073
Operating costs and expenses:					
Direct costs (excluding depreciation)	34,760	26,979	10,206	(4,748)	67,197
Selling	7,170	5,202	1,377	-	13,749
General and administrative	18,742	4,486	3,310	-	26,538
Research and development	1,757	8,725	-	-	10,482
Depreciation	3,661	2,764	1,330	-	7,755
Direct pharmaceutical start-up costs	-	2,123	-	-	2,123
	66,090	50,279	16,223	(4,748)	127,844
Income (loss) from operations	14,171	21,343	134	(22,419)	13,229
Other (expense) income:					
Interest, net	(1,377)	(2,123)	(146)	-	(3,646)
Net intercompany interest	(3,621)	3,781	(160)	-	-
Other	(182)	(477)	215	-	(444)
	(5,180)	1,181	(91)	-	(4,090)
Income (loss) before income taxes	8,991	22,524	43	(22,419)	9,139
Provision for income taxes	3,051	153	(5)	-	3,199
Net income (loss)	\$ 5,940	\$ 22,371	\$ 48	\$ (22,419)	\$ 5,940

aaiPharma Inc.
CONSOLIDATING BALANCE SHEET
(In thousands)

December 31, 2003

	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current assets:					
Cash and cash equivalents	\$ 8,161	\$ 192	\$ 432	\$ -	\$ 8,785
Accounts receivable, net	11,242	16,785	4,587	-	32,614
Work-in-progress	3,688	5,337	7,793	(4,315)	12,503
Inventories, net	4,588	8,909	1,196	-	14,693
Deferred tax assets	19,184	-	-	-	19,184
Prepaid and other current assets	1,872	8,304	222	-	10,398
Total current assets	48,735	39,527	14,230	(4,315)	98,177
Investments in and advances to subsidiaries	66,061	(46,202)	-	(19,859)	-
Property and equipment, net	39,011	13,954	4,271	-	57,236
Goodwill, net	725	1,229	11,407	-	13,361
Intangibles, net	1,209	350,106	-	-	351,315
Other assets	2,419	11,974	115	-	14,508
Total assets	<u>\$ 158,160</u>	<u>\$ 370,588</u>	<u>\$ 30,023</u>	<u>\$ (24,174)</u>	<u>\$ 534,597</u>
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Current maturities of long-term debt	\$ -	\$ 4,000	\$ -	\$ -	\$ 4,000
Accounts payable	5,082	14,292	2,505	-	21,879
Customer advances	6,441	8,101	4,807	(1,719)	17,630
Accrued wages and benefits	2,575	1,517	1,228	-	5,320
Interest payable	7	5,504	-	-	5,511
Deferred product revenue	-	45,664	-	-	45,664
Other accrued liabilities	8,640	4,332	(448)	(1,391)	11,133
Total current liabilities	22,745	83,410	8,092	(3,110)	111,137
Long-term debt, less current portion	8,000	330,844	-	-	338,844
Other liabilities	2,442	7,451	-	-	9,893
Investments in and advances to subsidiaries	127,363	(133,182)	6,212	(393)	-
Total stockholders' equity	(2,390)	82,065	15,719	(20,671)	74,723
Total liabilities and stockholders' equity	<u>\$ 158,160</u>	<u>\$ 370,588</u>	<u>\$ 30,023</u>	<u>\$ (24,174)</u>	<u>\$ 534,597</u>

aaiPharma Inc.
RESTATED CONSOLIDATING BALANCE SHEET
(In thousands)

December 31, 2002

	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current assets:					
Cash and cash equivalents	\$ 5,725	\$ 180	\$ 627	\$ -	\$ 6,532
Accounts receivable, net	10,104	16,758	2,605	-	29,467
Work-in-progress	4,135	2,951	4,568	(1,139)	10,515
Inventories, net	5,504	11,114	697	(311)	17,004
Deferred tax assets	1,271	-	-	-	1,271
Prepaid and other current assets	2,511	3,642	209	-	6,362
Total current assets	29,250	34,645	8,706	(1,450)	71,151
Investments in and advances to subsidiaries	66,061	(46,202)	-	(19,859)	-
Property and equipment, net	42,055	7,070	4,000	-	53,125
Goodwill, net	624	1,230	9,524	-	11,378
Intangibles, net	952	280,717	-	-	281,669
Other assets	4,514	11,569	96	-	16,179
Total assets	<u>\$ 143,456</u>	<u>\$ 289,029</u>	<u>\$ 22,326</u>	<u>\$ (21,309)</u>	<u>\$ 433,502</u>
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Current maturities of long-term debt	\$ -	\$ 5,921	\$ -	\$ -	\$ 5,921
Accounts payable	4,410	11,447	1,814	-	17,671
Customer advances	7,840	5,731	2,618	(1,138)	15,051
Accrued wages and benefits	4,922	929	867	-	6,718
Interest payable	285	4,947	-	-	5,232
Other accrued liabilities	1,244	3,379	(77)	655	5,201
Total current liabilities	18,701	32,354	5,222	(483)	55,794
Long-term debt, less current portion	47,500	230,399	-	-	277,899
Other liabilities	4,555	-	-	-	4,555
Investments in and advances to subsidiaries	68,094	(72,423)	4,984	(655)	-
Total stockholders' equity	4,606	98,699	12,120	(20,171)	95,254
Total liabilities and stockholders' equity	<u>\$ 143,456</u>	<u>\$ 289,029</u>	<u>\$ 22,326</u>	<u>\$ (21,309)</u>	<u>\$ 433,502</u>

aaiPharma Inc.
CONSOLIDATING STATEMENT OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2003				
	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Cash flows from operating activities:					
Net (loss) income	\$ (32,703)	\$ (17,574)	\$ 1,125	\$ 16,449	\$ (32,703)
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:					
Depreciation and amortization	5,039	14,034	1,173	-	20,246
Intangible asset impairment	-	20,600	-	-	20,600
Write-off of deferred financing and other costs	1,511	-	-	-	1,511
Other	(151)	(13)	598	-	434
Changes in operating assets and liabilities:					
Accounts receivable, net	(1,138)	(27)	(1,467)	-	(2,632)
Work-in-progress	447	(2,386)	(2,322)	3,176	(1,085)
Inventories, net	916	2,205	(361)	(311)	2,449
Deferred tax assets	(17,913)	-	-	-	(17,913)
Prepaid and other assets	1,224	(6,939)	28	-	(5,687)
Accounts payable	673	2,844	332	-	3,849
Customer advances	(1,399)	2,370	1,671	(580)	2,062
Interest payable	(277)	556	-	-	279
Deferred product revenue	-	45,664	-	-	45,664
Accrued wages and benefits and other accrued liabilities	2,935	1,540	(1,150)	(2,047)	1,278
Intercompany receivables and payables	76,218	(60,758)	1,227	(16,687)	-
Net cash provided by (used in) operating activities	<u>35,382</u>	<u>2,116</u>	<u>854</u>	<u>-</u>	<u>38,352</u>
Cash flows from investing activities:					
Purchases of property and equipment	(2,082)	(8,654)	(1,174)	-	(11,910)
Proceeds from sales of property and equipment	381	225	-	-	606
Acquisitions of product rights and other intangibles	-	(102,464)	-	-	(102,464)
Other	(502)	-	-	-	(502)
Net cash used in investing activities	<u>(2,203)</u>	<u>(110,893)</u>	<u>(1,174)</u>	<u>-</u>	<u>(114,270)</u>
Cash flows from financing activities:					
Proceeds from long-term borrowings	-	160,000	-	-	160,000
Payments on long-term borrowings	(39,500)	(54,000)	-	-	(93,500)
Proceeds from interest rate swaps, net	-	1,703	-	-	1,703
Proceeds from stock option exercises	8,757	-	-	-	8,757
Other	-	1,086	-	-	1,086
Net cash (used in) provided by financing activities	<u>(30,743)</u>	<u>108,789</u>	<u>-</u>	<u>-</u>	<u>78,046</u>
Net increase (decrease) in cash and cash equivalents	2,436	12	(320)	-	2,128
Effect of exchange rate changes on cash	-	-	125	-	125
Cash and cash equivalents, beginning of period	5,725	180	627	-	6,532
Cash and cash equivalents, end of period	<u>\$ 8,161</u>	<u>\$ 192</u>	<u>\$ 432</u>	<u>\$ -</u>	<u>\$ 8,785</u>

aaiPharma Inc.
RESTATED CONSOLIDATING STATEMENT OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2002				
	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Cash flows from operating activities:					
Net income (loss)	\$ 13,118	\$ 48,876	\$ (100)	\$ (48,776)	\$ 13,118
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:					
Depreciation and amortization	4,743	10,654	998	-	16,395
Write-off of deferred financing and other costs	-	8,053	-	-	8,053
Other	(9)	(432)	586	-	145
Changes in operating assets and liabilities:					
Accounts receivable, net	3,085	(8,342)	577	2,300	(2,380)
Work-in-progress	(264)	2,148	(80)	(1,161)	643
Inventories, net	(2,549)	(5,530)	(85)	311	(7,853)
Deferred tax assets	(352)	-	-	-	(352)
Prepaid and other assets	2,510	(13,007)	88	-	(10,409)
Accounts payable	783	1,211	(57)	-	1,937
Customer advances	3,957	(1,143)	(449)	(1,138)	1,227
Interest payable	284	4,577	-	-	4,861
Accrued wages and benefits and other accrued liabilities	5,634	238	(1,348)	1,056	5,580
Intercompany receivables and payables	(59,528)	11,199	935	47,394	-
Net cash (used in) provided by operating activities	<u>(28,588)</u>	<u>58,502</u>	<u>1,065</u>	<u>(14)</u>	<u>30,965</u>
Cash flows from investing activities:					
Purchases of property and equipment	(4,909)	(2,070)	(1,550)	-	(8,529)
Purchases of property and equipment previously leased	(14,145)	-	-	-	(14,145)
Proceeds from sales of property and equipment	127	4	-	-	131
Acquisitions of product rights and other intangibles	-	(211,997)	-	-	(211,997)
Other	(642)	49	-	-	(593)
Net cash used in investing activities	<u>(19,569)</u>	<u>(214,014)</u>	<u>(1,550)</u>	<u>-</u>	<u>(235,133)</u>
Cash flows from financing activities:					
Proceeds from long-term borrowings	49,401	195,085	-	-	244,486
Payments on long-term borrowings	(1,900)	(50,014)	-	14	(51,900)
Proceeds from interest rate swaps, net	-	10,486	-	-	10,486
Proceeds from stock option exercises	3,243	-	-	-	3,243
Other	(2,163)	(19)	29	-	(2,153)
Net cash provided by financing activities	<u>48,581</u>	<u>155,538</u>	<u>29</u>	<u>14</u>	<u>204,162</u>
Net increase (decrease) in cash and cash equivalents	424	26	(456)	-	(6)
Effect of exchange rate changes on cash	-	-	167	-	167
Cash and cash equivalents, beginning of period	5,301	154	916	-	6,371
Cash and cash equivalents, end of period	<u>\$ 5,725</u>	<u>\$ 180</u>	<u>\$ 627</u>	<u>\$</u>	<u>\$ 6,532</u>

-aaiPharma Inc.
CONSOLIDATING STATEMENT OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2001				
	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Cash flows from operating activities:					
Net income (loss)	\$ 5,940	\$ 22,371	\$ 48	\$ (22,419)	\$ 5,940
Adjustments to reconcile net income (loss) to net cash provided by operating activities:					
Depreciation and amortization	3,661	2,764	1,330	-	7,755
Other	449	458	358	-	1,265
Changes in operating assets and liabilities:					
Accounts receivable, net	4,238	(6,559)	(791)	-	(3,112)
Work-in-progress	4,358	(192)	2,336	-	6,502
Inventories, net	(30)	(5,519)	97	-	(5,452)
Deferred tax assets	2,597	-	-	-	2,597
Prepaid and other assets	783	(5,485)	(127)	-	(4,829)
Accounts payable	(430)	6,828	275	-	6,673
Customer advances	890	(406)	1,038	-	1,522
Interest payable	(144)	371	-	-	227
Accrued wages and benefits and other accrued liabilities	212	1,465	(12)	(402)	1,263
Intercompany receivables and payables	(9,099)	(12,917)	(819)	22,835	-
Net cash provided by operating activities	13,425	3,179	3,733	14	20,351
Cash flows from investing activities:					
Purchases of property and equipment	(174)	(4,821)	(1,320)	-	(6,315)
Proceeds from sales of property and equipment	2,792	645	76	-	3,513
Acquisitions of product rights and other intangibles	(983)	(78,117)	-	-	(79,100)
Other	151	-	-	-	151
Net cash provided by (used in) investing activities	1,786	(82,293)	(1,244)	-	(81,751)
Cash flows from financing activities:					
Net payments on short-term debt	(14,653)	-	(1,619)	-	(16,272)
Proceeds from long-term borrowings	-	78,878	-	-	78,878
Payments on long-term borrowings	(952)	(58)	-	(14)	(1,024)
Proceeds from stock option exercises	5,123	-	-	-	5,123
Other	(67)	(49)	(36)	-	(152)
Net cash (used in) provided by financing activities	(10,549)	78,771	(1,655)	(14)	66,553
Net increase (decrease) in cash and cash equivalents	4,662	(343)	834	-	5,153
Effect of exchange rate changes on cash	-	-	(7)	-	(7)
Cash and cash equivalents, beginning of year	639	497	89	-	1,225
Cash and cash equivalents, end of year	\$ 5,301	\$ 154	\$ 916	\$ -	\$ 6,371

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

None.

Item 9A. Disclosure Controls and Procedures

The Company has carried out an evaluation, under the supervision and with the participation of its newly appointed Chief Executive Officer and interim Chief Financial Officer, pursuant to Rule 13a-15 promulgated under the Securities Exchange Act of 1934, as amended, of the effectiveness of the design and operation of its disclosure controls and procedures as of December 31, 2003, the end of the period covered by this Annual Report on Form 10-K. Disclosure controls and procedures are to be designed to ensure that material information the Company must disclose in its reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported on a timely basis. As a result of that review, our Chief Executive Officer and interim Chief Financial Officer have concluded that, as of such date, the Company's disclosure controls and procedures were not adequate.

The internal control deficiencies related to, among other things, a lack of adequate policies with respect to revenue recognition, and a lack of sufficient control processes and procedures to effectively monitor and manage wholesaler inventory levels, to ensure adequate contract-approval oversight, and to ensure effective and timely communication among sales, marketing, finance and legal staff regarding the terms and conditions of certain transactions, including new product launches. Also, with respect to the sales of pharmaceutical products, the Company's finance and accounting personnel lacked adequate training on the application of revenue recognition principles and the establishment of product return reserves.

In addition, in April 2004, in connection with their audit of the Company's consolidated financial statements for the year ended December 31, 2003, the Company's independent auditors identified and communicated to the Company and the Audit Committee two "material weaknesses" (as defined under standards established by the American Institute of Certified Public Accountants) relating to the Company's accounting and public financial reporting of significant matters and to its initial recording and management review and oversight of certain accounting matters. The material weaknesses were with respect to the calculation and procedures for the analysis of revenue reserves for product sales and lack of procedures for timely communications from the Legal Department and operating divisions to the Finance Department impairing the ability to properly evaluate the accounting treatment for certain transactions the Company had entered into and assess the impact of such transactions in a timely manner. In addition, at that time, the Company's independent auditors identified and communicated to the Company and the Audit Committee a "reportable condition" (as defined under standards established by the American Institute of Certified Public Accountants) relating to the Company's internal controls over its financial reporting for investments. The reportable condition identified the Company's failure to perform a formal review of its investments and timely to record patents or trademarks or to timely analyze the patents and trademarks for usefulness and possible impairment.

In view of the fact that the financial information presented in this annual report was prepared in the absence of adequate internal controls over financial reporting, the Company devoted a significant amount of time and resources to the analysis of the financial information and documentation underlying the financial statements contained in this annual report, including the related interim financial statements, resulting in the restatement of certain interim financial statements. In particular, the Company reviewed significant product sales transactions to confirm the terms of the transaction and our accounting for the transaction, including whether all criteria for the recognition of revenue had been satisfied and whether we had properly estimated allowances for returns and other customer credits. In addition, the Company reviewed in detail each of the matters identified by the Special Committee and its independent counsel and independent forensic accountants. The investigation of the Special Committee is discussed in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Special Committee Investigation."

In light of the foregoing, the Company has taken the following actions, in addition to those described above, after the end of the fiscal year covered by this report to address the deficiencies as described above:

- reassigned all financial controllers from operating units into the Finance Department reporting to the Company's Controller and Chief Accounting Officer who reports directly to the Chief Financial Officer,
- commenced a company-wide education effort regarding our Code of Conduct and contract-approval policies,
- implemented a more vigorous contract-approval process,
- implemented formal revenue recognition protocols and training programs; and
- contracted with a third-party consulting group, FTI Consulting, to provide transitional management services in the area of operations and finance.

In addition, since December 31, 2003, the Company's then Chief Executive Officer, Chief Operating Officer and Chief Financial Officer have left the Company. In March of 2004, Dr. Sancilio, the Company's Executive Chairman and Chief Scientific Officer, was appointed Chief Executive Officer, and Gregory F. Rayburn, a consultant with FTI Consulting, was appointed Interim Chief Operating Officer. In April 2004, Timothy R. Wright was appointed President of the Company's Pharmaceuticals Products Division. Gina Gutzeit, another consultant with FTI Consulting, was appointed as interim Chief Financial Officer in May 2004.

The Company is fully committed to implementing controls identified by the Company's independent auditors and the Special Committee. The Company's efforts to strengthen its financial and internal controls continue, and the Company expects to complete remediation of the material weaknesses and reportable condition identified by its independent auditors by the end of 2004.

PART III

Item 10. Directors and Executive Officers of the Registrant

Directors

The business and affairs of the Company are managed under the direction of its Board of Directors, which is presently comprised of ten members. The Board of Directors is classified, with the directors serving staggered three-year terms. The following sets forth certain information with respect to our directors as of May 18, 2004.

James L. Waters (age 78) has served as a director of the Company since 1981 and as a non-employee officer from 1982 until 1996. Mr. Waters is a private investor in numerous companies, is president of Cetek Corporation, a drug discovery company, Secretary of Trans-Tek, Inc., an instrument measurement company, and is the founder of Waters Associates, Inc., now known as Waters Corporation, a scientific instrumentation manufacturer.

James G. Martin, Ph.D. (age 68) joined the Company's Board of Directors in 1999. Dr. Martin has served since 1995 as Corporate Vice President and since 1993 as Chairman of the Research Development Board of Carolinas HealthCare System, a regional healthcare system. Prior to joining Carolinas HealthCare, Dr. Martin served as Governor of the State of North Carolina from 1984 to 1992. Dr. Martin also serves as a director of Duke Energy Corporation, Palomar Medical Technologies, Inc., and Family Dollar Stores, Inc.

Kurt M. Landgraf (age 57) joined the Company's Board of Directors in 2001. Mr. Landgraf has served since August 2000 as the President and Chief Executive Officer of the Educational and Testing Service in Princeton, New Jersey, the world's largest private educational testing and measurement organization. He served in various positions at E.I. DuPont de Nemours Company and its affiliates from 1980 until 2000, including Chairman and Chief Executive Officer of DuPont Pharmaceuticals Company from January 2000 to May 2000, Executive Vice President and Chief Operating Officer from April 1998 to August 2000, Executive Vice President from November 1997 to April 1998, and Chief Financial Officer from December 1996 to October 1997 of E.I. DuPont de Nemours and Company. Mr. Landgraf serves as director of IKON Office Solutions, Inc., and NDC Health Corporation.

John E. Avery (age 75) joined the Company's Board of Directors in 2000. Mr. Avery is a retired senior executive of Johnson & Johnson, a leading multinational healthcare products company, having served as Company Group Chairman of all operations in Latin America and the Caribbean. Mr. Avery served from 1993 to 1996 as Chairman of each of the Americas Society and the Council of the Americas, each a non-profit organization.

Frederick D. Sancilio, Ph.D. (age 54) is Executive Chairman of the Board of Directors and Chief Scientific Officer of the Company. With more than 25 years experience in the pharmaceutical industry, Dr. Sancilio worked with Burroughs-Wellcome Co., Schering-Plough Corporation, and Hoffmann-LaRoche, Inc. before founding the Company in 1979.

William H. Underwood (age 56) is Executive Vice President, Corporate Development of the Company, and has served as Chief Operating Officer from 1995 to 1997, as Executive Vice President since 1992, as Vice President from 1986 to 1992, and as a director since 1996. He has held positions in the pharmaceutical and cosmetic industries for more than 17 years, in positions including Director of Quality Assurance and Director of Manufacturing at Mary Kay Cosmetics, Inc. and Group Leader of Bacteriological Quality Control at Burroughs-Wellcome Co.

John M. Ryan (age 59) has served as a director of the Company since 1996. Mr. Ryan serves as managing partner of Ryan Partners, a business advisory and venture capital firm he founded in July 1996 and vice president of Cetek Corporation, a drug discovery company. Prior to founding Ryan Partners, Mr. Ryan served as a partner of Coopers & Lybrand, LLP (now PricewaterhouseCoopers LLP), an accounting firm, with which he was associated from 1972 to 1996. Mr. Ryan has served as a director of numerous private companies and as an officer and director of several not-for-profit corporations.

Joseph H. Gleberman (age 46) joined the Company's Board of Directors in 1995. Mr. Gleberman has been employed by Goldman, Sachs & Co., an investment-banking firm, since 1982 and has been a Partner of Goldman, Sachs & Co. since 1990 and as Managing Director since 1996. Mr. Gleberman serves as a director of BackWeb Technologies Ltd., Berry Plastics Corporation, IPC Acquisition Corp. and MCG Capital Corporation. Pursuant to a stockholders' agreement entered into in connection with a 1995 investment in the Company, certain Goldman Sachs investment partnerships have the right to designate one member of the Company's Board of Directors for as long as the investment partnerships collectively own at least 10% of the Company's outstanding Common Stock. Mr. Gleberman is their nominee.

Richard G. Morrison, Ph.D. (age 67) joined the Company's Board of Directors in 1999. Prior to his retirement in May 2001, Dr. Morrison was an Adjunct Professor of Business at the Cameron School of Business, University of North Carolina at Wilmington for over six years. Dr. Morrison also has more than 30 years of pharmaceutical industry experience, recently acting as a private consultant for medium-sized international pharmaceutical businesses, and having served as General Manager and President of Eli Lilly's operations in Venezuela, Mexico and Brazil.

Timothy R. Wright joined the Company in April 2004 as President of the Pharmaceuticals Division and was elected a director in May 2004. Prior to joining the Company, Mr. Wright served as the President, Global Commercial Operations for Elan Bio-pharmaceuticals from February 2001 to December 2003, as well as a member of Elan Pharmaceuticals, Inc. Prior to Elan, Mr. Wright served as a Senior Vice President of Healthcare Product Services with Cardinal Health, Inc. from May 1999 to January 2001. Mr. Wright also held senior management positions with DuPont Merck Pharmaceutical Company from 1984 to 1999.

Executive Officers

The following table contains information concerning our executive officers as of May 18, 2004:

Name	Age	Position
Frederick D. Sancilio, Ph.D.	54	Chief Executive Officer and President
Timothy R. Wright	46	President, Pharmaceuticals Division
Vijay Aggarwal, Ph.D.	55	President, Research & Development
Gregory F. Rayburn	45	Interim Chief Operating Officer
Gina Gutzeit	42	Interim Chief Financial Officer
William H. Underwood Development	56	Executive Vice President, Business
Gregory S. Bentley Counsel	54	Executive Vice President and General

Frederick D. Sancilio, Ph.D. has been a Director since 1979, and is currently Executive Chairman of the Board of Directors and Chief Executive Officer of aaiPharma. Before founding aaiPharma in 1979, Dr. Sancilio's experience in the pharmaceutical industry included various positions with Burroughs-Wellcome Co., Schering-Plough Corporation, and Hoffmann-LaRoche, Inc. Dr. Sancilio served as the Chairman of the Board of Directors and Chief Executive Officer of aaiPharma since the Company was founded until July 1, 2002 and resumed this role in March 2004.

Timothy R. Wright joined the Company in April 2004 as President of the Pharmaceuticals Division and was elected a director in May 2004. Prior to joining the Company, Mr. Wright served as the President, Global Commercial Operations for Elan Bio-pharmaceuticals from February 2001 to December 2003, as well as a member of Elan Pharmaceuticals, Inc. Prior to Elan, Mr. Wright served as a Senior Vice President of Healthcare Product Services with Cardinal Health, Inc. from May 1999 to January 2001. Mr. Wright also held senior management positions with DuPont Merck Pharmaceutical Company from 1984 to 1999.

Vijay Aggarwal, Ph.D. has served as President of Research and Development for aaiPharma since January 2004, having previously served as Executive Vice President of aaiPharma and as President of AAI International since April 2002. Prior to joining aaiPharma, Dr. Aggarwal served from August 1999 to January 2001 as the President of the Quest Diagnostic Ventures division of Quest Diagnostics Inc., a provider of diagnostic testing, information and services. From 1985 to 1999, Dr. Aggarwal served in various positions at Smithkline Beecham Clinical Laboratories, Inc., an independent clinical laboratory, including as the Vice President and Director of US Laboratories from July 1998 to August 1999 and as the Vice President and Director of Managed Care from 1994 to 1998.

Gregory F. Rayburn joined the company as interim Chief Operating Officer in March 2004. Mr. Rayburn is also a senior managing director and the Interim Management practice leader with FTI Consulting, a leading provider of turnaround, performance improvement, financial and operational restructuring services. Mr. Rayburn provides services to us through a contract between the Company and FTI Consulting. Mr. Rayburn joined FTI Consulting in 2003. Prior to FTI Consulting, Mr. Rayburn served as a principal with AlixPartners from 2000 to 2003. While at AlixPartners, Mr. Rayburn served as the Chief Restructuring Officer of WorldCom. Prior to AlixPartners, Mr. Rayburn served from 1998 to 2000 as the president of

The Capstone Group LLC, a private investment partnership. Prior to Capstone Mr. Rayburn was a partner in the Corporate Recovery Services Group of Arthur Andersen LLP.

Gina Gutzeit became our interim Chief Financial Officer in May 2004. Ms. Gutzeit is a senior managing director in FTI Consulting's Corporate Finance/Restructuring practice. FTI Consulting is a leading provider of turnaround, performance improvement, financial and operational restructuring services. Ms. Gutzeit has been a senior managing director since September 2002. Prior to September 2002, Ms. Gutzeit was a partner with PricewaterhouseCoopers LLP in the Business Recovery Services group. The Business Recovery Services group was acquired by FTI Consulting on August 30, 2002. She joined PricewaterhouseCoopers in 1996.

William H. Underwood is a Director and Executive Vice President -- Corporate Development of aaiPharma. He has served as a Director since 1996, as Chief Operating Officer from 1995 to 1997, as Executive Vice President since 1992, and as Vice President from 1986 to 1992. Mr. Underwood held various positions in the pharmaceutical and cosmetic industries prior to joining aaiPharma in 1986, including Director of Quality Assurance and Director of Manufacturing at Mary Kay Cosmetics, Inc. and Group Leader of Bacteriological Quality Control at Burroughs-Wellcome Co.

Gregory S. Bentley has served as Executive Vice President and General Counsel of aaiPharma since June 1999. Mr. Bentley served as Secretary of aaiPharma from June 1999 to April 2002. Prior to joining aaiPharma, Mr. Bentley served from 1994 to 1999 as Vice President, Regulatory and Quality for Siemens Medical Systems, Inc., a leading medical device company and a subsidiary of Siemens Corporation. Prior to joining Siemens Corporation as Associate General Counsel in 1986, Mr. Bentley practiced law with the law firm of Shearman & Sterling in New York.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 (the "Exchange Act") requires the Company's officers and directors, as well as any holders of more than 10% of the Company's Common Stock, to file with the SEC certain reports of ownership and changes in ownership of Common Stock and other equity securities of the Company. Based solely on review of such reports and certain representations furnished to it, the Company believes that during the fiscal year ended December 31, 2003, all officers and directors complied with all applicable Section 16(a) filing requirements, except that Dr. Sancilio was late in reporting a purchase of Common Stock that occurred on March 24, 2003. The report was filed on March 31, 2003.

Audit Committee

The Board of Directors has determined that the members of the Audit Committee are independent as defined in Rule 4200(a)(15) of the National Association of Securities Dealers' listing standards. The audit committee is composed of James G. Martin, Ph.D., Richard G. Morrison, Ph.D., and Kurt M. Landgraf. The Board of Directors has also determined that Mr.

Landgraf is an "audit committee financial expert" as defined in Item 401(h) of Regulation S-K.

Code of Ethics

In addition to a code of conduct that applies to all of our employees, our Board of Directors has adopted a code of ethics that applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and Controller. We will provide copies of our code of ethics without charge upon request. To obtain a copy of the code of ethics free of charge, please send your written request to our General Counsel, aaiPharma Inc., 2320 Scientific Park Drive, Wilmington, North Carolina 28405.

Item 11. Executive Compensation

Compensation of Directors

All non-employee directors receive \$3,000 per meeting for attending in person meetings of the Board of Directors and meetings of Board committees not held in connection with a regular Board meeting. Non-employee directors also receive \$1,000 per meeting lasting longer than one hour for participating in telephonic meetings of the Board of Directors and \$500 for Board committee telephonic meetings. In addition, non-employee directors who serve on the Audit and the Executive and Corporate Governance Committees receive an annual retainer of \$15,000 and \$10,000, respectively. Each non-employee chair of the Audit, the Executive and Corporate Governance and the Compensation Committees receives an annual retainer of \$30,000, \$15,000 and \$10,000, respectively. Directors are also reimbursed for expenses incurred in connection with attending meetings.

Executive Compensation

The following Summary Compensation Table sets forth all compensation awarded to, earned by or paid for services rendered to the Company in all capacities in 2003 by: (i) the Company's chief executive officer and (ii) the Company's next four most highly compensated employees who were serving as executive officers on December 31, 2003 (collectively, the "Named Executive Officers"):

Summary Compensation Table

Long Term Compensation Awards

Name and Principal Position	Year	<u>Annual Compensation</u>			Restricted Stock Awards (#)	Securities Underlying Options/SARs (#)	All Other Compensation(\$)
		<u>Salary (\$)</u> (1)	<u>Bonus (\$)</u> (2)	<u>Other Annual Compensation</u>			
Frederick D. Sancilio, PhD Executive Chairman and Chief Scientific Officer	2003	438,193	100,000	73,125(3)	0		0
	2002	407,115	427,000	58,499(4)	0	82,500	0
	2001	400,000	0	(5)	0	67,500	0
Philip S. Tabbiner, D.B.A. (6) President & Chief Executive Officer	2003	527,500	26,375		0	329,500	3,000
	2002	397,942	360,500	(5)	37,500	168,000	0
	2001	285,000	0	(5)	0	12,000	65,160(7)
David M. Hurley (8) Executive Vice President	2003	374,063	18,703	(5)	0	142,750	766
	2002	309,615	161,000	(5)	0	300,000	0
	2001	-	-	-	-	-	-
William L. Ginna, Jr. (9) Executive Vice President & Chief Financial Officer	2003	274,301	13,175	(5)	0	157,750	3,000
	2002	260,000	197,300	30,000(10)	0	187,500	3,000
	2001	209,750	0	(5)	0	0	3,000
Gregory S. Bentley Executive Vice President & General Counsel	2003	237,375	11,869	(5)	0	27,500	3,000
	2002	225,000	219,250	(5)	0	75,000	3,000
	2001	184,750	30,000	(5)	0	0	3,000
Vijay Aggarwal, Ph.D. (11) Executive Vice President	2003	356,645	17,832	(5)		142,750	2,675
	2002	232,212	59,875(12)	0	0	0	0
	2001	-	-	-	-	-	-

- (1) Includes salary amounts deferred pursuant to the Company's 401(k) plan.
- (2) Includes discretionary bonuses granted in March 2002 that were paid in 2003 and 2004; performance bonuses for 2002 that were paid in 2003; bonuses paid in 2003 for regulatory approval of Company products; and one bonus deferred in 2001 and paid in 2003. Discretionary bonuses were granted in March 2002 and were payable in April 2002, unless the executive elected to defer receipt of the bonus until the future. If the deferral election was made, the executive received 100% of the bonus in January 2003 and received an additional 100% of the bonus in January 2004, unless the deferring executive voluntarily left our employment prior to the payment date. The following listed executives elected to defer the bonus payment and received the following amounts in each of 2003 and 2004, and the aggregate of the bonuses received is reflected in the executive's 2002 bonus line: Dr. Sancilio, \$140,000; Dr. Tabbiner, \$99,750; Mr. Ginna, \$75,250 and Mr. Bentley, \$66,500. In addition, Mr. Bentley received a \$30,000 bonus in 2002 and an equal amount that was deferred until 2003. Both bonus payments are reflected in Mr. Bentley's 2002 bonus. The named executives received bonuses for 2002 performance in the following amounts, which are included in the 2002 bonus line: Dr. Sancilio, \$147,000; Dr. Tabbiner, \$161,000; Mr. Hurley, \$161,000; Mr. Ginna, \$46,800; Mr. Bentley, \$56,250; and Dr. Aggarwal, \$25,875. The executives also received bonuses upon the commercialization of certain products which received regulatory approval in 2003, in the following amounts: Dr. Sancilio, \$100,000; Dr. Tabbiner, \$26,375; Mr. Hurley, \$18,703; Mr. Ginna, \$13,715; Mr. Bentley, \$11,869; and Dr. Aggarwal, \$17,832. No bonuses were paid to executives as a result of their individual or collective performance during 2003.

- (3) Such amounts include \$62,230 for non-business use of the Company's aircraft and \$10,895 for reimbursement for accounting fees and club memberships pursuant to Dr. Sancilio's employment agreement with the Company.
- (4) Such amounts include \$24,414 for non-business use of the Company's aircraft and \$20,946 for reimbursement for accounting fees and club memberships pursuant to Dr. Sancilio's employment agreement with the Company.
- (5) Amounts received do not exceed the lesser of \$50,000 or 10% of salary.
- (6) Dr. Tabbiner left the Company on March 29, 2004.
- (7) Relocation expense reimbursement.
- (8) Mr. Hurley commenced employment with us on February 4, 2002 and left the Company on February 13, 2004.
- (9) Mr. Ginna left the Company on May 10, 2004.
- (10) Includes reimbursement of \$24,000 for a country club membership.
- (11) Dr. Aggarwal commenced employment with the Company on April 22, 2002.
- (12) Includes signing bonus of \$34,000.

The following table sets forth certain information with respect to options granted during 2003 to the executive officers named in the Summary Compensation Table.

Stock Option Grants in 2003

Name and Principal Position	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term (1)	
	Number of Securities Underlying Options Granted (#) (2)	Percent of Total Options/SARs Granted to Employees in Fiscal Year	Exercise Price (\$/Sh)	Expiration Date		
Frederick D. Sancilio, Ph.D.	0	-	-	-	-	-
Philip S. Tabbiner, D.B.A.	304,500 25,000	16.2% 1.3%	14.65 17.98	5/30/13 11/20/13	2,805,452 282,609	7,109,566 716,188
David M. Hurley	117,750 25,000	6.2% 1.3%	14.65 17.98	5/30/12 11/20/13	1,084,667 282,609	2,749,266 716,188
William L. Ginna, Jr.	132,750 25,000	7.0% 1.3%	14.65 17.98	5/30/13 11/20/13	1,223,066 282,609	3,099,490 716,188
Gregory S. Bentley	7,500 10,000 10,000	0.4% 0.5% 0.5%	12.65 14.59 17.98	2/19/13 6/3/13 11/20/13	59,681 91,724 113,044	151,242 232,447 286,475
Vijay Aggarwal, Ph.D.	117,750 25,000	6.2% 1.3%	14.65 17.98	5/30/13 11/20/13	1,084,667 282,609	2,749,266 716,188

- (1) Potential realizable value is based on an assumption that the price of the Common Stock appreciates at the annual rate shown (compounded annually) from the date of grant until the end of the ten-year option term. The numbers are calculated based on the requirements promulgated by the SEC and do not reflect the Company's estimate of future stock price growth.
- (2) The options vest in one-third increments at each of the first, second, and third anniversaries of the grant date except that the options granted on May 30, 2003 vest on the seventh anniversary of the grant date, but may vest sooner in the following

proportions if the closing price equals or exceeds the following targets for a period of seven consecutive days: 25%, \$22.67; 50%, \$34.00; 75%, \$45.33; and 100%, \$55.67.

The following table sets forth certain information with respect to the number of shares underlying unexercised options and the value of unexercised options held at fiscal year end by the Named Executive Officers:

Aggregated 2003 Year-End Option Values

Name and Principal Position	Number of Securities Underlying Unexercised Options at Fiscal Year- End(%) Exercisable/Unexercisable		Value of Unexercised In-the-Money Options At Fiscal Year-End(1) Exercisable/Unexercisable	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Frederick D. Sancilio, Ph.D.	140,000	77,500	2,434,925	930,753
Philip S. Tabbiner, D.B.A.	231,876	374,624	3,466,912	4,126,925
David M. Hurley	117,564	325,187	1,507,699	4,026,809
William L. Ginna, Jr.	197,546	260,206	3,226,470	3,048,223
Gregory S. Bentley	129,977	77,523	2,362,541	857,501
Vijay Aggarwal, Ph.D.	117,523	325,228	828,621	2,485,862

- (1) Market value of underlying securities at fiscal year end minus the exercise price of “in-the-money” options.

Employment and Compensation Agreements

On November 17, 1995, the Company entered into an employment agreement with Dr. Frederick D. Sancilio. The employment agreement was amended in 2003. The employment agreement renews automatically for successive two-year periods unless either party notifies the other party of an intention not to extend the term. Dr. Sancilio currently serves as aaiPharma’s Executive Chairman of the Board and Chief Executive Officer. From July 2002 to March 29, 2004, he served as Executive Chairman of the Board and Chief Scientific Officer. Prior to July 2002, he served as Chairman of the Board of Directors and Chief Executive Officer. The Company is required under this agreement to use best efforts to cause Dr. Sancilio to be elected to the Company’s board of directors, the boards of directors of any of affiliated corporations on which Dr. Sancilio served on November 17, 1995, and the board of directors of any majority-owned subsidiary of aaiPharma acquired after November 17, 1995.

In July 2002, Dr. Sancilio’s salary was adjusted downward to \$400,000 to reflect his new role as Executive Chairman and Chief Scientific Officer. The Board of Directors increased Dr. Sancilio’s annual salary from \$400,000 to \$422,000 effective January 1, 2003. Dr. Sancilio resumed his previous role as Chief Executive Officer on March 29, 2004. His salary has not yet been adjusted to reflect his increased responsibilities. Pursuant to the employment agreement, Dr. Sancilio receives a bonus when aaiPharma receives certain regulatory approvals. This bonus will be in the amount of \$250,000 for each new drug application and \$50,000 for each supplemental new drug application or abbreviated new drug application. Dr.

Sancilio was awarded a bonus of \$100,000 in March 2003 upon regulatory approval and commercialization of two products.

The employment agreement permits the Company to terminate Dr. Sancilio's employment at any time, with or without cause. However, if the Company terminates Dr. Sancilio's employment without cause or if Dr. Sancilio terminates his employment within 90 days after a "constructive discharge," Dr. Sancilio would be entitled to receive payments aggregating three times his then current annual salary. These payments would be made in monthly installments over two years, during which time Dr. Sancilio would continue to receive his medical and life insurance benefits. Under the employment agreement, a "constructive discharge" includes, among other things, the removal of Dr. Sancilio from the positions of Chairman of the Board, a reduction in Dr. Sancilio's responsibilities, or the relocation of the Company's principal executive offices by more than 30 miles from its current location. The employment agreement requires Dr. Sancilio to refrain from certain activities in competition with aaiPharma for a period of two years after the termination of his employment for any reason.

Other than Dr. Sancilio's agreement described above, no executive officer of the Company has an employment contract with aaiPharma.

On March 29, 2004, we announced that Dr. Tabbiner resigned to take a consulting position with us. Dr. Tabbiner entered into a consulting agreement with us for a period of fifteen months. Dr. Tabbiner agreed to provide such services as may be reasonably requested by the Company. Dr. Tabbiner is to receive \$10,615 per week during the term of the agreement. The consulting agreement ends in June 2005 or earlier if it is determined that Dr. Tabbiner committed an act of willful misconduct while serving as an employee of the Company.

On May 11, 2004, our Chief Financial Officer, William L. Ginna, Jr., left the Company. Mr. Ginna also agreed to enter into a consulting agreement, for a twelve-month period. Mr. Ginna is to receive \$6,173 per week during the term of the agreement. The consulting agreement ends in May 2005 or earlier if it is determined that Mr. Ginna committed an act of willful misconduct or gross negligence in the performance of his duties as an employee of the Company.

Item 12. Security Ownership of Certain Beneficial Owners and Management

Security Ownership

The following table sets forth certain information known to aaiPharma with respect to beneficial ownership of aaiPharma's common stock as of May 15, 2004 by (i) each stockholder known by aaiPharma to be the beneficial owner of more than 5% of aaiPharma's common stock, (ii) each director, (iii) each executive officer named in the Summary Compensation Table and (iv) all executive officers and directors as a group.

Name of Beneficial Owner	Number of Shares Beneficially Owned (1)	Percent of Shares (2)
Frederick D. Sancilio, Ph.D. (3)(4)	6,313,167	21.9%
Brown Capital Management, Inc. (5)	4,495,150	15.7%
The Goldman Sachs Group, Inc. (6)	3,415,249	11.9%
James Waters (7)	3,326,254	11.6%
Royce Associates, LLC (8)	1,440,600	5.0%
Arnold H. Snider (9)	1,780,000	6.2%
John E. Avery	154,995	*
Joseph H. Gleberman (10)	4,995	*
Kurt M. Landgraf	76,295	*
James G. Martin, Ph.D.	115,744	*
Richard Morrison, Ph.D.	107,494	*
John M. Ryan	125,495	*
William H. Underwood (11)	301,929	1.0%
Timothy R. Wright	0	*
Phillip S. Tabbiner, D.B.A.	286,629	1.0%
Gregory S. Bentley	175,287	*
William L. Ginna, Jr.	217,526	*
David M. Hurley	0	*
All executive officers and directors as a group (18 persons)	10,964,808	37.6%

* Less than 1%

- (1) Unless otherwise indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable. Information in the table reflects options granted under aaiPharma's 1995 Stock Option Plan, 1996 Stock Option Plan, 1997 Stock Option Plan and the 2000 Non-Employee Director Stock Option Plan to the extent such options are or become exercisable within 60 days. Accordingly, the totals for the following executive officers and directors and all executive officers and directors as a group includes the following shares represented by options: Mr. Ryan, 124,995 shares; Mr. Underwood, 174,833 shares; Dr. Martin, 115,744 shares; Dr. Morrison, 107,494 shares; Mr. Gleberman, 4,995 shares; Mr. Bentley, 155,787 shares; Dr. Sancilio, 190,000 shares; Mr. Waters, 4,995 shares; Mr. Avery, 124,995 shares; Mr. Landgraf, 74,295 shares; Mr. Ginna, 217,526 shares; Mr. Hurley, 0 shares; Dr. Tabbiner, 245,376 shares; and all executive officers and directors as a group, 1,753,086 shares.
- (2) These calculations are based on an aggregate of 28,585,582 shares issued and outstanding as of May 15, 2004. Options to purchase shares held by a person that are exercisable or become exercisable within the 60-day period after May 15, 2004 are deemed to be outstanding for the purpose of calculating the percentage of outstanding shares owned by that person but are not deemed to be outstanding for the purpose of calculating the percentage owned by any other person.
- (3) Dr. Sancilio's address is 1001 North Highway 1, Suite 308, Jupiter, Florida 33477.
- (4) Includes 2,325 shares owned by Dr. Sancilio's children.

- (5) Based on the Schedule 13G/A filed by Brown Capital Management, Inc. with the SEC on February 11, 2004. The address of Brown Capital Management, Inc. is 1201 N. Calvert Street, Baltimore, Maryland 21202. This Schedule 13G/A indicates that Brown Capital Management, Inc. has sole dispositive power for 4,495,150 shares and sole voting power for 2,516,145 shares.
- (6) Goldman, Sachs & Co. is a wholly-owned, direct and indirect, subsidiary of The Goldman Sachs Group, Inc. Goldman, Sachs, an NASD member, is an investment banking firm that regularly performs services such as acting as a financial advisor and serving as principal or agent in the purchase and sale of securities. The Goldman Sachs Group and Goldman, Sachs may be deemed to own beneficially and indirectly in the aggregate 3,415,249 shares of aaiPharma's common stock through certain investment partnerships of which affiliates of Goldman, Sachs and The Goldman Sachs Group are the general partner, managing general partner or managing partner. Each investment partnership shares voting and dispositive power with respect to its shares with The Goldman Sachs Group, Goldman, Sachs and certain of their affiliates. Goldman, Sachs is the investment manager of one or more of the investment partnerships. The address of Goldman, Sachs is 85 Broad Street, New York, New York 10004.
- (7) Includes 659,207 shares of common stock beneficially owned by Mr. Waters' spouse and 46,275 shares owned by the Waters Foundation. Mr. Waters and his spouse are the only trustees of the Waters Foundation. Mr. Waters' address is 47 New York Avenue, Framingham, Massachusetts 01701.
- (8) Based on Schedule 13G filed by Royce & Associates, LLC with the SEC dated January 31, 2003. The address of Royce & Associates, LLC is 1414 Avenue of Americas, New York, NY 10019. This Schedule 13G indicates that Royce & Associates, LLC has sole dispositive power for 1,440,600 shares and sole voting power for 1,440,600 shares.
- (9) Based on the Schedule 13G filed with the SEC on February 20, 2004 by Arnold H. Snider, Deerfield Capital, L.P., Deerfield Partners LP, Deerfield Management Company and Deerfield International Limited. Mr. Snider's address is 780 Third Avenue, 37th Floor, New York, NY 10017. This Schedule 13G indicates that Mr. Snider has shared dispositive power for 1,780,000 shares and shared voting power for 1,780,000 shares.
- (10) Mr. Gleberman, a managing director of Goldman, Sachs, disclaims beneficial ownership of the 3,415,249 shares that may be deemed beneficially owned by The Goldman Sachs Group as described in note (6) above. Mr. Gleberman, a managing director of Goldman, Sachs, disclaims beneficial ownership of the securities reported herein except to the extent of his pecuniary interest therein, if any.
- (11) Includes 1,387 shares owned by Mr. Underwood's children.

Equity Compensation Plan Information

The following table sets forth the aggregate number of options issued and available for issuance as of December 31, 2003 and the weighted average exercise price of the outstanding options in each case.

<u>Plan Category</u>	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	6,426,854	\$12.27	1,031,587
Equity compensation plans not approved by security holders	0	0	0
TOTAL	6,426,854	\$12.27	1,031,587

Item 13. Certain Relationships and Related Transactions

We have certain relationships, and have engaged in transactions, with related parties. These transactions may raise conflicts of interest and, although we do not have a formal policy to address conflicts of interest, we evaluate relationships and transactions involving conflicts of interest on a case by case basis.

In November 1995, GS Capital Partners II, L.P., G.S. Capital Partners II Offshore, L.P., Bridge Street Fund 1995, L.P., Stone Street Fund, L.P., and Goldman Sachs & Co. Verwaltungs GmbH, each an investment partnership managed by an affiliate of The Goldman Sachs Group Ltd., purchased shares of preferred stock of aaiPharma. All outstanding shares of preferred stock were converted into aaiPharma common stock in conjunction with our public offering of common stock in September 1996. These Goldman Sachs investment partnerships own 3,415,248 shares of our common stock. Pursuant to a stockholder agreement entered into in connection with their 1995 investment, the Goldman Sachs investment partnerships have the right to designate one member of our board of directors for so long as they and their affiliates (which include Goldman, Sachs & Co.) beneficially own 10% or more of the outstanding shares of our common stock. Pursuant to the stockholders agreement, Joseph Gleberman, a managing director of Goldman, Sachs & Co., serves as one of our directors.

In connection with the 1995 investment, we agreed that so long as the Goldman Sachs investment partnerships beneficially own 5% or more of the outstanding shares of our common stock, we will retain Goldman, Sachs & Co. or an affiliate to perform all investment banking services for us for which an investment banking firm is retained, and to serve as managing underwriter of any offering of our capital stock on customary terms, consistent with an arm's length transaction. If we cannot agree to the terms of an engagement with Goldman, Sachs & Co. or their affiliates after good faith discussions, the agreement permits us to engage any other investment banking firm. However, Goldman, Sachs & Co. would be entitled to serve as co managing underwriter in any underwritten offering of our capital stock.

In addition, in that 1995 investment transaction, we granted to the Goldman Sachs investment partnerships, and other stockholders including Frederick Sancilio, James Waters and William

Underwood, all current directors of aaiPharma, rights to cause us to register for sale the shares of common stock they beneficially owned at that time.

In 1994, as part of our internal development program, we organized Endeavor Pharmaceuticals, Inc. to continue development of products that we had been developing on our own. We assigned our rights to these products to Endeavor in return for approximately 47% of Endeavor's fully diluted equity. We also entered into a contract with Endeavor to continue product development and clinical supply manufacture and granted to Endeavor, under certain circumstances, the first right to purchase additional proprietary hormone pharmaceutical products that we develop. Although this contract terminated in April 2001, Endeavor's right to purchase internally developed hormone products that we develop continued through April 2004. In the fourth quarter of 2003, Endeavor sold substantially all of its assets to Barr Laboratories, Inc. As part of this transaction, we recorded a pretax gain of \$1.8 million for the sale of our investment in Endeavor. Also in December 2003, Endeavor filed articles of dissolution with the Delaware Secretary of State.

Pursuant to our product development and supply agreements with Endeavor, we had net sales to Endeavor of approximately \$0.6 million in 2003, \$1.1 million in 2002 and \$0.2 million in 2001. These amounts were charged at our commercial rates similar to those charged to other clients. At December 31, 2003, we had no related accounts receivable and at December 31, 2002, we had \$0.3 million in related accounts receivable. In February 2000, we purchased product rights to an estradiol product and validated manufacturing equipment from Endeavor as consideration for reducing Endeavor's outstanding receivable and work in progress balances. Endeavor assigned to us the rights to this estradiol product, a generic version of estradiol approved by the FDA, and the related commercialization contract between Endeavor and a third party. Under the commercialization agreement, we will be entitled to certain minimum royalties if the third party manufactures and distributes estradiol. Endeavor also sold a piece of manufacturing equipment and related accessories to us. As consideration for these product and contract rights and equipment, we agreed to reduce Endeavor's outstanding receivable balance from approximately \$2.9 million, including work in progress, to \$950,000. The terms of this transaction resulted from negotiations between Endeavor and us. We believe this transaction was fair to us based on our estimate of the value of the outstanding receivable and work in process balances we reduced compared to the value of the rights and equipment we acquired.

We organized Aesgen, Inc. with an affiliate of the Mayo Clinic in 1994 and funded it in 1995 with an affiliate of the Mayo Clinic, MOVA Pharmaceutical Corporation and certain other investors. Our initial common stock investment in Aesgen was distributed to our shareholders prior to our initial public offering in 1996. As a result, our directors and executive officers beneficially own the following percentages of the fully diluted common equity of Aesgen as of December 31, 2003: Dr. Sancilio, 3.7%, Mr. Waters, 9.4% (including shares owned by his spouse and the Waters Foundation) and Mr. Underwood, 0.3%. In addition, the Goldman Sachs investment partnerships own 1.8% of the fully diluted common equity of Aesgen as of December 31, 2003. In January 2001, the terms of the nonconvertible, redeemable preferred stock we received in connection with our 1995 investment in Aesgen were amended to make that class of stock convertible into Aesgen common stock. In October 2001 we agreed to provide development services to Aesgen, through AAI Development Services, in exchange for

up to \$1.1 million of Aesgen convertible preferred stock. Through December 31, 2003, the Company had performed \$580,000 of services under the agreement. As of December 31, 2003, we owned 10.0% of the common equity of Aesgen on a fully diluted basis. We do not anticipate performing any additional services for Aesgen under this agreement.

At the time of our 1995 investment in Aesgen, we entered into a development agreement with Aesgen. Under this agreement, we had the right to provide product development and support services to Aesgen with respect to the generic drugs being developed by Aesgen, provided that our fees for such services were comparable to those of a competitor. In addition, we were obligated not to develop for our own account or for any other person, any formulation of the generic products then under development by Aesgen. In 1996, we sold to Aesgen marketing rights to a pharmaceutical product that we were developing. Under the agreement, Aesgen paid a license fee and will pay additional royalties upon marketing the product. In December 2001 we agreed to purchase from Aesgen a number of generic product development projects including the rights to associated abbreviated new drug applications that have been filed with or approved by the FDA. In exchange for the rights to these products, we agreed to terminate the 1995 development agreement and the 1996 license agreement with Aesgen described above, and to release Aesgen from any and all liabilities owed to us under these contracts, including approximately \$0.7 million of work in progress and accounts receivable. Furthermore, as a result of this transaction, we will have the right to receive royalties that were formerly payable to Aesgen by MOVA Pharmaceutical Corporation with respect to the abbreviated new drug applications we acquired from Aesgen. The terms of this transaction resulted from negotiations between Aesgen and us. We believe this transaction was fair to us.

In February 2002, we purchased a proprietary product from Aesgen for payments of \$1.0 million in cash and additional contingent milestone payments of up to \$1.5 million. In 2003, the prerequisite for payment of an additional \$500,000 of such contingent milestones occurred and such payment was made to Aesgen, while the prerequisites for payment of the remaining \$1.0 million were not met and no further payment of this amount is potentially owed by the Company. We market this product as an extension of the Aquasol product line. Under this agreement, we are obligated to pay royalty payments for the eight-year period following the first commercial sale of this product. In 2003, we expensed royalties related to this agreement of \$0.6 million. Of this amount, none was payable at December 31, 2003.

We recognized net revenues of zero, \$494,000 and \$86,000 from Aesgen in 2003, 2002, and 2001, respectively and we had no accounts receivable or work in progress at December 31, 2003 or 2002.

Mr. Waters and Dr. Sancilio have agreed to sell us up to a total of 363,807 shares of our common stock to provide the shares for issuance pursuant to our 1995 Stock Option Plan. Upon the exercise of a stock option awarded under the 1995 plan, we are entitled to purchase from them the same number of shares at the exercise price of the option, \$5.57 per share. As of December 31, 2003, no options were outstanding to acquire shares of our common stock under our 1995 Stock Option Plan. We acquired 4,202 shares in 2003 for \$23,388 from Mr. Waters, no shares in 2002 and 39,198 shares in 2001 for \$218,202, and we acquired 5,715 shares in 2003 for \$28,590 from Dr. Sancilio, no shares in 2002 and 47,910 shares in 2001 for \$266,699.

Item 14. Principal Accountant Fees and Services

Fees Paid to Independent Auditors

Audit Fees

The Company has incurred fees of \$884,921 and \$1,905,870 in 2002 and 2003, respectively, for services rendered for the audits of the Company's consolidated financial statements, including restatement of previously issued financial statements, timely reviews of Forms 10-Q, consents, issuance of comfort letters, assistance with review of documents filed with the SEC and statutory audits of various international subsidiaries.

Audit-Related Fees

The Company has been billed \$330,921 and \$451,873 for services rendered in 2002 and 2003, respectively, for accounting consultations and due diligence related to acquisitions, assistance with internal control reporting requirements, audit services concerning the Company's 401k plan, and various audit related consultations concerning financial accounting and reporting standards.

Tax Fees

Aggregate fees billed for all tax compliance, tax advice and tax planning services rendered in 2002 and 2003 are \$378,657 and \$722,795. These fees are primarily for services rendered in the areas of international tax planning, transfer pricing consultation, research and development tax credits, state and local tax preparation assistance, tax compliance and general tax consulting.

All Other Fees

No other fees were paid to our independent auditors in 2002 and 2003.

Pre-approval Policy

On January 29, 2003, the Audit Committee of our Board of Directors adopted the policy described below regarding the pre-approval of all audit and permissible non-audit services provided by the independent auditor after such date. Prior to engagement of the independent auditor for the next year's audit, management is required to submit an aggregate of services expected to be rendered during that year for each of the four categories of services listed below to the audit committee for approval.

- Audit services, which include audit work performed in the preparation of financial statements, as well as work that generally only the independent auditor can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.
- Audit-related services for assurance and related services that are traditionally performed by the independent auditor, such as due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

- Tax services, which include services performed by the independent auditor's tax personnel other than services specifically related to the audit of the financial statements, such as tax compliance, tax planning, and tax advice.
- Other services, which include services not captured in the other categories.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted and the Audit Committee requires the independent auditor and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise that make it necessary to engage the independent auditor for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval of the services before engaging the independent auditor.

The audit committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

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

(a)(1) and (2)--The response to this portion of Item 15 is submitted as a separate section of this report and reference is hereby made to Item 8.

(b) During the fourth quarter of 2003, we furnished the following current reports on Form 8-K:

- dated October 3, 2003, to furnish a press release announcing financial results for the period ended September 30, 2003 and the execution of agreements to acquire a portfolio of pain management products from Elan Corporation, plc.
- dated December 15, 2003, to furnish a press release announcing the completion of the previously announced acquisition from Elan Pharmaceuticals, Inc. and Elan Pharma Limited of the U.S. and U.S. territorial rights and related intangibles associated with the Roxicodone, Oramorph SR, Roxanol and Duraclon.

(c) Exhibits--A list of the exhibits required to be filed as part of this Report on Form 10-K is set forth in the "Exhibit Index", which immediately precedes such exhibits, and is incorporated herein by reference.

(d) FINANCIAL STATEMENT SCHEDULE

Schedules not included herein have been omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

SCHEDULE II

aaiPharma Inc.

VALUATION AND QUALIFYING ACCOUNTS

(In thousands)

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Charged to Other Accounts	Deductions	Balance at End of Period
Allowance for doubtful accounts					
2001	\$ 829	\$ 970	\$ 268 (2)	\$ (1,023) (1)	\$ 1,044
2002	1,044	1,294	-	(670) (1)	1,668
2003	1,668	1,181	-	(1,871) (1)	978
Product inventory obsolescence reserves					
2001	-	281	-	(81) (3)	200
2002	200	526	-	(5) (3)	721
2003	721	11,688	-	(1,650) (3)	10,759
Tax asset valuation allowances					
2001	2,520	129	-	-	2,649
2002 (as restated)	2,649	362	-	-	3,011
2003	3,011	11,185	-	-	14,196

-
- (1) Represents amounts written off as uncollectible accounts receivable
 - (2) Represents allowance on accounts assumed in acquisition
 - (3) Represents amounts disposed

SIGNATURES

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

/s/ Frederick D. Sancilio, Ph.D. Executive Chairman of the Board and June 15, 2004
Frederick D. Sancilio, Ph.D. Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons, or in their behalf by their duly appointed attorney-in-fact, on behalf of the Registrant in the capacities and on the date indicated.

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
<u>/s/ FREDERICK D. SANCILIO, PH.D.</u> Frederick D. Sancilio, Ph.D.	Executive Chairman of the Board, Chief Executive Officer and Director.	June 15, 2004
<u>/s/ GINA GUTZEIT</u> Gina Gutzeit	Interim Chief Financial Officer	June 15, 2004
<u>/s/ JOHN D. HOGAN</u> John D. Hogan	Vice President and Controller (Principal Accounting Officer)	June 15, 2004
<u>/s/ WILLIAM H. UNDERWOOD</u> William H. Underwood	Executive Vice President and Director	June 15, 2004
<u>/s/ Timothy R. Wright</u> Timothy R. Wright	Executive Vice President and Director	June 15, 2004
<u>/s/ JOHN E. AVERY</u> John E. Avery	Director	June 15, 2004
<u>/s/ JOSEPH H. GLEBERMAN</u> Joseph H. Gleberman	Director	June 15, 2004
<u>/s/ KURT M. LANDGRAF</u> Kurt M. Landgraf	Director	June 15, 2004
<u>/s/ JAMES G. MARTIN</u> James G. Martin, Ph.D.	Director	June 15, 2004
<u>/s/ RICHARD G. MORRISON</u> Richard G. Morrison, Ph.D.	Director	June 15, 2004
<u>/s/ JOHN M. RYAN</u> John M. Ryan	Director	June 15, 2004
<u>/s/ JAMES L. WATERS</u> James L. Waters	Director	June 15, 2004

aaiPharma Inc.
Exhibit Index

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of the Company, and amendments thereto (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003)
3.2	Amended By laws of the Company (incorporated by reference to Exhibit 3.3 to the Company's Quarterly Report on Form 10 Q for the quarter ended June 30, 2000)
4.1	Articles Fourth, Seventh, Eleventh and Twelfth of the form of Amended and Restated Certificate of Incorporation of the Company (included in Exhibit 3.1)
4.2	Article II of the form of Restated By laws of the Company (included in Exhibit 3.2)
4.3	Specimen Certificate for shares of Common Stock, \$.001 par value, of the Company (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S 1 (Registration No. 333 5535))
4.4	Indenture (which includes the form of 11% senior subordinate note due 2010) dated as of March 28, 2002 between the Company, certain of its subsidiaries as guarantors and Wachovia Bank, National Association (formerly, First Union National Bank), as Trustee (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 (Registration No. 333-85602) filed with the SEC on April 5, 2002)
4.5	First Supplemental Indenture, dated as of April 20, 2004, among the Company, certain of its subsidiaries as guarantor parties thereto and Wachovia Bank, National Association (formerly, First Union National Bank), as Trustee (incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K filed with the SEC on April 27, 2004)
4.6	Security Agreement, dated as of April 23, 2004, made by the Company and certain subsidiaries of the Company as grantors in favor of Wachovia Bank, National Association, in its capacity as collateral agent for the holders of the Company's 11% Senior Subordinated Notes due 2010 (incorporated by reference to Exhibit 99.5 to the Company's Current Report on Form 8-K filed with the SEC on April 27, 2004)
4.7	Pledge and Security Agreement, dated as of April 23, 2004, made by the Company and certain subsidiaries of the Company as pledgors in favor of Wachovia Bank, National Association, in its capacity as collateral agent for the holders of the

Company's 11% Senior Subordinated Notes due 2010 (incorporated by reference to Exhibit 99.6 to the Company's Current Report on Form 8-K filed with the SEC on April 27, 2004)

- 10.1 Amended and Restated Employment Agreement dated January 1, 2003 between the Company and Frederick D. Sancilio (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2003)*
- 10.2 Applied Analytical Industries, Inc. 1995 Stock Option Plan (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (Registration No. 333-5535))*
- 10.3 Applied Analytical Industries, Inc. 1996 Stock Option Plan, as amended on March 27, 2000 (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K filed for the year ended December 31, 1999)*
- 10.4 Applied Analytical Industries, Inc. 1997 Stock Option Plan, as amended, (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2003)*
- 10.5 aaiPharma Inc. 2000 Stock Option Plan for Non-Employee Directors, as amended (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (Registration No. 333-85602))
- 10.6 Stockholder Agreement dated as of November 17, 1995 among the Company, GS Capital Partners II, L.P., GS Capital Partners II Offshore, L.P., Goldman, Sachs & Co. Verwaltungs GmbH, Stone Street Fund 1995, L.P., Bridge Street Fund 1995, L.P., Noro-Moseley Partners III, L.P., Wakefield Group Limited Partnership, James L. Waters, Frederick D. Sancilio and the parties listed on Schedule 1 thereto (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (Registration No. 333-5535))
- 10.7 Registration Rights Agreement dated as of November 17, 1995 among the Company, GS Capital Partners II, L.P., GS Capital Partners II Offshore, L.P., Goldman, Sachs & Co. Verwaltungs GmbH, Stone Street Fund 1995, L.P., Bridge Street Fund 1995, L.P., Noro-Moseley Partners III, L.P., Wakefield Group Limited Partnership, James L. Waters, Frederick D. Sancilio and the parties listed on Schedule 1 thereto (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (Registration No. 333-5535))
- 10.8 Underwriting Agreement dated September 19, 1996 between the Company and Goldman Sachs & Co., Cowen & Company and Lehman Brothers, Inc., as representatives of the underwriters listed on Schedule 1 thereto (incorporated by

reference to Exhibit 10.17 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996)

- 10.9 Asset Purchase Agreement by and between AstraZeneca AB and NeoSan Pharmaceuticals Inc. dated as of July 25, 2001 (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2001)
- 10.10 First Amendment to Asset Purchase Agreement dated as of July 22, 2003 between aaiPharma LLC (formerly, NeoSan Pharmaceuticals Inc.) and AstraZeneca AB (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2003)
- 10.11 Interim Supply Agreement dated as of August 17, 2001 between NeoSan Pharmaceuticals Inc. and AstraZeneca L.P. (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K dated January 22, 2002)
- 10.12 First Amendment to Interim Supply Agreement dated as of July 22, 2003 between aaiPharma LLC (formerly, NeoSan Pharmaceuticals Inc.) and AstraZeneca L.P. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2003)
- 10.13 Asset Purchase Agreement dated as of December 13, 2001 between NeoSan Pharmaceuticals Inc., Novartis Pharmaceuticals Corporation and Novartis Corporation (incorporated by reference to Exhibit 2.3 to the Company's Current Report on Form 8-K dated January 22, 2002)
- 10.14 Interim Supply Agreement dated as of December 13, 2001 between NeoSan Pharmaceuticals Inc. and Novartis Pharmaceuticals Corporation (incorporated by reference to Exhibit 2.3 to the Company's Current Report on Form 8-K dated January 22, 2002)
- 10.15 Assignment, Transfer and Assumption Agreement dated as of February 18, 2002 between NeoSan Pharmaceuticals, Inc. and Eli Lilly and Company (incorporated by reference to Exhibit 2.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A dated April 12, 2002)
- 10.16 Manufacturing Agreement dated as of February 18, 2002 between NeoSan Pharmaceuticals, Inc. and Eli Lilly and Company (incorporated by reference to Exhibit 2.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A dated April 12, 2002)
- 10.17 Asset Purchase Agreement dated as of October 22, 2003 by and among aaiPharma Inc., Elan Pharma International Limited and Elan Pharmaceuticals, Inc.

(incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated December 12, 2003)

- 10.18 Roxanne Assignment and Assumption Agreement dated as of October 22, 2003 by and among aaiPharma Inc., Elan Pharma International Limited, Elan Pharmaceuticals, Inc., Elan Corporation, plc, Roxane Laboratories, Inc. and Boehringer Ingelheim Corporation (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K dated December 12, 2003)
- 10.19 First Amendment to Manufacturing Agreement dated as of December 2, 2003 by and between Elan Pharma International Limited and Roxane Laboratories, Inc. (incorporated by reference to Exhibit 2.3 to the Company's Current Report on Form 8-K dated December 12, 2003)
- 10.20 Asset Purchase Agreement dated as of July 16, 2003 by and among aaiPharma Inc. and Athlon Pharmaceuticals, Inc.
- 10.21 Service Agreement dated as of July 16, 2003 by and among aaiPharma Inc. and Athlon Pharmaceuticals, Inc.
- 10.22 Manufacturing and Supply Agreement dated as of July 16, 2003 by and between aaiPharma Inc. and Mikart, Inc.
- 10.23 First Amendment to Manufacturing and Supply Agreement dated as of May 13, 2004 between aaiPharma Inc. and Mikart, Inc.
- 10.24 Subscription Agreement dated as of October 19, 2001 between the Company and Aesgen, Inc. (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2001)
- 10.25 Product Sales Agreement dated as of December 21, 2001 between the Company and Aesgen, Inc. (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2001)
- 10.26 Asset Purchase Agreement dated as of February 27, 2004, among aaiPharma Inc., a Delaware corporation, aaiPharma LLC, a Delaware limited liability company, AAI Properties, Inc., a North Carolina corporation and Mayne Pharma (USA) Inc., a Delaware corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated May 7, 2004)
- 10.27 Amendment No. 1 to Asset Purchase Agreement dated as of April 22, 2004, among aaiPharma Inc., a Delaware corporation, aaiPharma LLC, a Delaware limited liability company, AAI Properties, Inc., a North Carolina corporation and Mayne Pharma (USA) Inc., a Delaware corporation (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K dated May 7, 2004)

- 10.28 Credit Agreement dated as of March 28, 2002 between the Company, certain of its subsidiaries, the lenders from time to time party thereto, and Bank of America, N.A., as administrative agent (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 (Registration No. 333-85602))
- 10.29 First Amendment to Credit Agreement dated as of December 1, 2003 between aaiPharma Inc., certain subsidiaries of aaiPharma Inc., the lenders party thereto, and Bank of America, N.A., as administrative agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K dated December 12, 2003)
- 10.30 Financing Agreement (the "Financing Agreement"), dated as of April 23, 2004, by and among the Company and certain subsidiaries of the Company as borrowers, the financial institutions from time to time party thereto as lenders, Silver Point Finance, LLC, as collateral agent, and Bank of America, N.A., as administrative agent (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K dated April 27, 2004)
- 10.31 Security Agreement, dated April 23, 2004, made by the Company and certain subsidiaries of the Company as grantors in favor of Silver Point Finance, LLC, as collateral agent, and the lenders party to the Financing Agreement (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K dated April 27, 2004)
- 10.32 Pledge and Security Agreement, dated April 23, 2004, made by the Company and certain subsidiaries of the Company as pledgors in favor of Silver Point Finance, LLC, as collateral agent, and the lenders party to the Financing Agreement (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K dated April 27, 2004)
- 10.33 Intercreditor Agreement, dated as of April 23, 2004, among Silver Point Finance, LLC, as senior collateral agent, Wachovia Bank, National Association, as noteholder collateral agent, and the Company (incorporated by reference to Exhibit 99.7 to the Company's Current Report on Form 8-K dated April 27, 2004)
- 18 Letter regarding change in accounting policy
- 21 Subsidiaries of aaiPharma Inc. (incorporated by reference to Exhibit 21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002)
- 23 Consent of Ernst & Young LLP
- 31.1 Certification pursuant to Exchange Act Rule 13a – 14(a) of Frederick D. Sancilio
- 31.2 Certification pursuant to Exchange Act Rule 13a – 14(a) of Gina Gutzeit

* Management contract or compensatory plan required to be filed under Item 15(c) of this report and Item 601 of Regulation S-K of the SEC.

December 4, 2003

Board of Directors

aaiPharma Inc.
2320 Scientific Park Drive
Wilmington, North Carolina 28403

Note 1 of the notes to the audited consolidated financial statements of aaiPharma Inc. included in its Annual Report on Form 10-K for the period ended December 31, 2003 describes a change in the date (from December 31 to October 1) of the Company's annual goodwill impairment test required under Statement of Financial Accounting Standards ("SFAS") No. 142, *Goodwill and Other Intangible Assets*. There are no authoritative criteria for determining a 'preferable' measurement date for this analysis based on the particular circumstances; however, we conclude that such a change in the method of applying SFAS No. 142 is to an acceptable alternative date which, based on your business judgment to make this change and for the stated reasons, is preferable in your circumstances.

Very truly yours,

/s/ Ernst & Young LLP

Consent of Independent Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-89020, 333-78453, 333-50877, 333-74515, 333-67114 and 333-50841) and the Registration Statement (Form S-1 No. 333-85602) and the related Prospectus of our report dated May 14, 2004, with respect to the consolidated financial statements and schedule of aaiPharma Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2003.

/s/ Ernst & Young LLP

Raleigh, North Carolina
June 14, 2004

CERTIFICATION

I, Frederick D. Sancilio, certify that:

1. I have reviewed this annual report on Form 10-K for the year ending on December 31, 2003 of aaiPharma Inc. (the "registrant") ;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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: June 11, 2004

/s/ Frederick D. Sancilio
Dr. Frederick D. Sancilio
Executive Chairman and Chief Executive Officer

CERTIFICATION

I, Gina Gutzeit, certify that:

1. I have reviewed this annual report on Form 10-K for the year ending on December 31, 2003 of aaiPharma Inc. (the "registrant") ;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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: June 11, 2004

/s/ Gina Gutzeit

Gina Gutzeit

Interim Chief Financial Officer

CERTIFICATION

The undersigned officers of the registrant certify that, to their knowledge, the annual report on Form 10-K for the annual period ending December 31, 2003 fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 780(d)) and that information contained in this report fairly presents, in all material respects, the financial condition and results of operation of the registrant as of the dates and for the periods expressed in the report.

Date: June 11, 2004

/s/ Frederick D. Sancilio
Dr. Frederick D. Sancilio
Executive Chairman and Chief Executive Officer

Date: June 11, 2004

/s/ Gina Gutzeit
Gina Gutzeit
Interim Chief Financial Officer