

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K *ARS*

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the fiscal year ended July 31, 2005

OR

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

For the transition period from to

Commission file number 0-17521

**Zila, Inc.**

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

5227 North 7th Street,  
Phoenix, Arizona

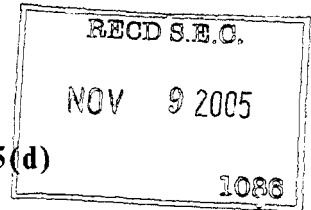
(Address of Principal Executive Offices)

86-0619668

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

85014-2800

(Zip Code)



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THOMSON FINANCIAL

Registrant's telephone number, including area code  
(602) 266-6700

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

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
None	N/A

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

Common Stock, \$.001 par value  
(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 a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

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

At January 31, 2005, the end of our second fiscal quarter, the aggregate market value of common stock held by non-affiliates of the registrant was approximately \$179.5 million based on the closing price of \$3.92 as reported on the Nasdaq National Market. At September 30, 2005, the number of shares of common stock outstanding was 45,891,550.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information contained in the registrant's definitive proxy statement for the annual meeting of stockholders to be held on December 15, 2005 has been incorporated by reference into Part III, Items 10, 11, 12, 13 and 14.

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## PART I

### Item 1. *Business*

Zila, Inc. is an innovator in preventive healthcare technologies and products, focusing on enhanced body defense and the detection of pre-disease states. In this report, "Zila," the "Company," "we," "us," or "our" refer to Zila, Inc. and its wholly-owned subsidiaries. Zila, Inc. is a holding company that conducts its business operations through three Business Units: Nutraceuticals, Pharmaceuticals and Biotechnology.

The Nutraceuticals Business Unit ("Nutraceuticals") manufactures and markets Ester-C<sup>®</sup>, a patented, branded, highly effective form of vitamin C sold by us into 20 countries around the world, and Ester-E<sup>®</sup>, a proprietary, branded, enhanced form of vitamin E whose first commercial shipments commenced in May 2004 in the United States. The Nutraceuticals Business Unit previously included Oxycal Laboratories, Inc., an Arizona corporation ("Oxycal"), and its subsidiary, Zila Nutraceuticals, Inc., also an Arizona corporation. In January 2005, Oxycal was merged with its subsidiary and was renamed Zila Nutraceuticals, Inc.

The Pharmaceuticals Business Unit ("Pharmaceuticals") includes the ViziLite<sup>®</sup> chemiluminescent disposable light product, and the adjunct product ViziLite<sup>®</sup> Plus with T-Blue<sup>630™</sup>, for the illumination and marking of oral mucosal abnormalities, Peridex<sup>®</sup> prescription periodontal rinse, and the plastic molded products of Zila Swab Technologies, Inc., an Arizona corporation dba Innovative<sup>®</sup> Swab Technologies ("IST"). The Zilactin<sup>®</sup> family of over-the-counter products was sold in June 2005. The Pharmaceuticals Business Unit includes Zila Pharmaceuticals, Inc., a Nevada corporation, and IST.

The Biotechnology Business Unit is our research, development and licensing division specializing in pre-cancer/cancer detection through its patented Zila Tolonium Chloride and OraTest<sup>®</sup> technologies and manages the OraTest<sup>®</sup> product, an oral cancer diagnostic system. The Biotechnology Business Unit includes: Zila Biotechnology, Inc., an Arizona corporation; Zila Technical, Inc., an Arizona corporation; and Zila Limited, a United Kingdom company.

### Recent Developments

During the fiscal year ended July 31, 2005 ("Fiscal 2005"), we made progress in the furtherance of our OraTest<sup>®</sup> regulatory program. We believe that our on-going dialog with the United States Food and Drug Administration ("FDA") is progressing and continues to be productive. We have successfully resolved questions involving the primary endpoints of our clinical trial, the appropriate statistical measures to be used to evaluate the trial results and other matters related to the regulatory program. The program is designed to reduce the duration and cost of the original program while improving the potential market by assessing the efficacy of OraTest<sup>®</sup> in selecting and staining cancerous and pre-cancerous oral lesions in a broad population of tobacco users and alcohol drinkers.

We anticipate that patient enrollment in the new Phase III regulatory program will begin by the end of calendar 2005. We further believe that we can complete the study as early as twelve months from the enrollment of the first patients, although no assurances can be given in either regard. The trial is expected to require no more than 4,000 patients who generally undergo a single visit. Upon completion of the clinical trial and assuming that the clinical endpoints have been achieved, we estimate that it will require approximately three months to prepare the new drug application supplement for submission to the FDA.

In June 2005, we completed the sale of the Zilactin<sup>®</sup> brand of over-the-counter products to a third party. Cash proceeds of the sale totaled approximately \$11.0 million. The financial statements included herein reflect the treatment of the economic activity of the Zilactin line as discontinued operations. (See Note 3 of the Notes to Consolidated Financial Statements for further discussion.)

Plans are proceeding for the official launch of our ViziLite<sup>®</sup> Plus product at the October 2005 annual meeting of the American Dental Association with sales anticipated to commence late in our second fiscal quarter. ViziLite<sup>®</sup> Plus is a combination product that includes the ViziLite<sup>®</sup> chemiluminescent device to identify abnormalities in the oral mucosa and a TBlue<sup>630™</sup> marking device to mark the identified lesions for further evaluation.

We have a human clinical trial currently underway and a second trial protocol being developed in support of our Ester-E<sup>®</sup> product. The United States market for single supplement forms of vitamin E was negatively impacted by research work that was published during fiscal 2005 that, in some cases, questioned the benefit of vitamin E supplementation and, in other cases, actually suggested that vitamin E supplementation might be harmful beyond certain dosage levels. We do not believe that the conclusions of these studies are valid as they relate to vitamin E supplementation by healthy individuals or to Ester-E<sup>®</sup> specifically. The launch of our Ester-E<sup>®</sup> product was made more difficult by these publications. The clinical work that we are doing in support of Ester-E<sup>®</sup> is directed to differentiating Ester-E<sup>®</sup> from other forms of vitamin E that are currently available, as well as seeking to demonstrate the safety and other healthful properties of the product.

In October 2005, we terminated an agreement with a principal of Barrington Research that had provided for certain consulting and financial advisory services.

Financial information for our Business Units for each of the last three fiscal years is included in our Consolidated Financial Statements and the notes thereto.

## **Our Products**

### *Nutraceuticals*

#### *Ester-C<sup>®</sup>*

Ester-C<sup>®</sup> is a unique and patented form of vitamin C containing natural vitamin C metabolites that help it work differently than other forms of vitamin C. It is natural, non-acidic and gentle to the stomach. Products manufactured with Ester-C<sup>®</sup> nutritional ingredients are sold by us into 20 countries worldwide. We require our customers to display the federally registered Ester-C<sup>®</sup> logo on their packaging. Ester-C<sup>®</sup> ingredients are primarily used in dietary supplements and are available to consumers at retail under approximately 300 brand names distributed by leading supplement manufacturers and marketers.

The principal forms in which we sell Ester-C<sup>®</sup> are bulk granular and powdered Ester-C<sup>®</sup> calcium ascorbate plus metabolites. We also distribute Ester-C<sup>®</sup> ingredients in a variety of product line extensions. Ester-C<sup>®</sup> Topical Concentrate, a liquid formulation for skin care products, provides a stable form of vitamin C that penetrates to the collagen-producing layers of the skin. Specialty grades of Ester-C<sup>®</sup> nutritional ingredients are available for use in multivitamins (Ester-C<sup>®</sup> MV), chewable vitamins (Ester-C<sup>®</sup> CG) and effervescent products (Ester-C<sup>®</sup> EG). Ester-C<sup>®</sup> Chelated Mineral Blend provides the benefits of supplemental vitamin C for animals. During fiscal 2005, we also launched an Ester-C<sup>®</sup> soft chew product that is a sweet, candy-like form of Ester-C<sup>®</sup>. Opportunities also exist both in new applications and forms of Ester-C<sup>®</sup>, including personal care, functional foods and fortified beverages, as well as in new distribution channels (e.g. multi-level marketing.)

We hold four United States and corresponding foreign patents on certain compositions and methods for administering vitamin C and therapeutically active compounds, one patent on a stable liquid form of mineral ascorbate, and we were issued a patent in the United States for methods and compositions for increasing the effectiveness of cancer chemotherapy agents with Ester-C<sup>®</sup> technology. Sales of Ester-C<sup>®</sup> accounted for approximately 84%, 74% and 67% of our net revenues for fiscal years 2005, 2004 and 2003, respectively. In fiscal 2005, our revenues from two customers, NBTY, Inc. and Natrol, Inc., are each in excess of 10% of consolidated net revenues.

#### *Ester-E<sup>®</sup>*

Ester-E<sup>®</sup> is an enhanced vitamin E formed by joining natural d-alpha tocopherol to a phosphate molecule in a patent-protected process. This process creates tocopheryl phosphates, a concentrated form of a naturally occurring ester of vitamin E. Ester-E<sup>®</sup> is designed to protect the antioxidant potential of vitamin E during absorption, transport and storage in the body to assist in the delivery of its nutritional benefits when needed. We plan to conduct human clinical trials during fiscal 2006 to support the results of preliminary animal studies that suggest specific health benefits related to Ester-E<sup>®</sup>. We sell Ester-E<sup>®</sup> as a bulk ingredient to nutraceutical

manufacturers and promote it directly to consumers through brand-building national advertising under a marketing and distribution model similar to our Ester-C® products.

Our license agreements with Vital Health grant us the exclusive rights in the human dietary supplement market for certain issued and pending patents, know-how and data pertaining to tocopheryl phosphates in the United States, Canada and Indonesia. Our arrangements with Vital Health also grant us extensive rights in the animal dietary supplement market in these countries. We have a right of first refusal for other international markets under such agreement, the initial term of the licensing agreement expires in 2008 but which we can unilaterally extend for the life of the underlying patents. Eight patents have been issued in Australia, the United States and/or South Africa, while other applications are pending. Commercial shipments of Ester-E® commenced in May 2004.

### ***Pharmaceuticals***

#### ***ViziLite®***

ViziLite® is a patented, FDA-cleared device for enhancing visualization of oral tissue abnormalities in patients at high risk for oral cancer. It consists of a disposable, chemiluminescent, low-wavelength light. The wavelengths of light produced are absorbed by normal cells, but are reflected by any abnormal cells. Using ViziLite® during a visual examination, normal cells appear dark, while abnormal cells appear bright white. The ViziLite® kit includes a small bottle of 1% acetic acid solution used prior to the procedure to disrupt the glycoprotein barrier of mucosal surfaces.

In January 2005 the Food and Drug Administration cleared the combination product, ViziLite® Plus, to be marketed as an adjunct to a ViziLite® examination. ViziLite® Plus is an oral examination system that contains the ViziLite® chemiluminescent device to identify abnormalities in the oral mucosa and a TBlue<sup>630™</sup> marking device to further evaluate the identified lesions for patients at increased risk for oral cancer. We plan to introduce our ViziLite® Plus product at the October 2005 annual meeting of the American Dental Association with sales anticipated to commence late in our second fiscal quarter. The TBlue<sup>630™</sup> marking device uses Zila Tolonium Chloride (“ZTC™”) to mark lesions.

#### ***Peridex®***

Peridex® is a prescription antibacterial oral rinse used between dental visits as part of a professional program for the treatment of gingivitis and periodontal disease. Known as the “gold standard” among dentists, Peridex® is highly recognized due to the product’s proven efficacy and longevity in the market. The active ingredient in Peridex® is 0.12% chlorhexidine gluconate. Peridex® is the first and only rinse to receive the American Dental Association Seal of Acceptance for reduction of plaque and gingivitis. Peridex® effectively controls the oral bacteria associated with periodontal disease, particularly in the first and only completely reversible stage, gingivitis. Controlling gum disease at its earliest stage is important because, if left untreated, gingivitis can progress to periodontitis, resulting in destruction of the periodontal structure and supporting bone.

### ***IST Products***

IST manufactures three sizes of dry handled swab applicators for original equipment manufacturer (“OEM”) customers and other of our products. IST also manufactures a proprietary brand of disposable probe covers (plastic sheaths for electronic thermometers) sold to healthcare distributors and custom plastic parts for OEM customers.

### ***Biotechnology***

#### ***OraTest®***

Zila Tolonium Chloride (“ZTC™”) is the active ingredient in OraTest® and is a patented form of pharmaceutical grade toluidine blue. In numerous studies, the technology behind ZTC™ has been shown to have a propensity toward staining lesions with a high risk of progressing to oral cancer and pre-cancer, leaving

non-cancerous lesions unstained. The potential applications for ZTC™ may include detecting high-risk lesions of the skin, cervix and esophagus as well as oral cancer, for which OraTest® is currently designed.

The OraTest® product is a patented system designed to be an aid in the early detection of oral squamous cell carcinoma. OraTest® consists of a ZTC™ aqueous solution with acetic acid and alcohol, and acetic acid pre- and post-rinse solutions. It is a diagnostic adjunct for oral cancer and may be used as a general rinse for detecting oral cancer in patients at elevated risk for oral cancer and as an aid to establish borders for biopsy and surgical site selection, applied as a chair-side oral rinse and swab and administered by either a medical practitioner or dentist. OraTest® contains the active ingredient ZTC™, a staining agent that has been reported in medical literature to stain cells within the mouth that are cancer and pre-cancer and that may not be otherwise visible to physicians or dentists. Research has shown that OraTest® may detect lesions on the progression pathway to oral cancer which still appear to be normal under the microscope.

According to the Oral Cancer Foundation, approximately 30,000 new oral cavity and pharyngeal cancers are being diagnosed each year in the United States, resulting in the death of approximately 50% of the people affected within five years. Oral cancer remains one of the most debilitating and disfiguring of all malignancies. In most people diagnosed with oral cancer, the disease has metastasized, resulting in a poor prognosis because the usual method of detecting the disease is a visual examination that only results in the identification of early cancers 35% of the time. Those who do survive frequently undergo disfiguring surgery. When oral cancer is detected early, survival rates are about 80%; detected late, the survival rate reportedly falls to 20%.

We are concentrating our efforts and investments on a regulatory program to support our application for approval of the OraTest® product in the United States by the FDA.

The product has already been approved for distribution in the United Kingdom, Australia, Belgium, Holland, Luxembourg, Finland, Greece, Portugal, Bermuda and the Bahamas.

## **Sales and Marketing**

### *Nutraceuticals*

#### *Ester-C® and Ester-E®*

We market Ester-C® and Ester-E® products through an atypical but highly effective business model for the vitamin supplement market, selling patent-protected bulk vitamin ingredients to supplement manufacturers and marketers and driving demand for these products through branded consumer advertising and public relations. Our multi-million dollar marketing program is designed to generate significant Ester-C® and Ester-E® awareness and use among current vitamin C and E consumers. The marketing program utilizes national television and radio advertising, communicating the benefits of supplementation with Ester-C® and Ester-E®. We also work closely with our manufacturer/marketer customers to support their efforts at gaining broad scale retail distribution and key retailer display and promotion. While Ester-C® retains a strong position in natural food outlets, its most significant recent growth has been achieved in the food, drug and mass retail channel. We are exploring new distribution channels in fiscal year 2006 such as multi-level marketing. Ester-E® was launched in the United States market late in fiscal year 2004 and is promoted directly to consumers through brand-building national advertising. International sales of Ester-C® are accomplished through local distributors, who receive our assistance in public relations and advertising. We are developing plans that we anticipate will strengthen our international distribution.

### *Pharmaceuticals*

#### *Peridex®*

Peridex® is currently concentrated in two focused channels of distribution: (i) direct to dental and (ii) retail pharmacies. We market Peridex® direct to dental healthcare professionals through an exclusive distribution arrangement with Omnii Oral Pharmaceuticals, Inc. of West Palm Beach, FL ("Omnii"), a national dental sales and distribution organization. Omnii has a national network of field sales representatives

with significant coverage of dental practices, dental and dental hygiene schools, as well as managed care organizations, pharmacists and wholesalers. We also utilize Omnii to fulfill our shipments to national wholesalers, which supply the second channel of distribution, the retail pharmacy industry.

#### *ViziLite®*

In order to achieve the vision of establishing ViziLite® and our new adjunct product, ViziLite® Plus with T-Blue<sup>630™</sup>, as the standard of care for oral abnormality screening, the overall strategy is to educate the dental professional and widen distribution. Through a combination of independent sales representatives and regional distributors, we have initially focused on five key geographical markets that have demonstrated early acceptance. Market expansion will be primarily generated by the following drivers: the development of self-study training through offline and online continuing education programs; the expansion of the field selling effort based on achievement of success metrics in existing focus markets; a comprehensive program targeting insurers designed to secure a meaningful level of insurance reimbursement for use of the ViziLite® device now that the new ADA codes have been published; and completion and effective communication of information about current and planned clinical efficacy trials that can provide thought leader support, involvement and commitment to the ViziLite® concept.

#### *IST Products*

IST markets its swab products to a variety of OEM accounts in the dental, medical and cosmetic industries using independent sales representatives and its own in-house employees. Probe covers are sold through local, regional and national distributors and buying groups.

#### *Biotechnology*

##### *OraTest®*

We sell the OraTest® product through our wholly-owned subsidiary, Zila Limited, in the United Kingdom. During fiscal 2003 we stopped promoting the product in Europe in favor of funding the FDA clinical trials. As of July 1, 2004, we entered into agreement with Scope Advertising and Marketing Services, Ltd. for limited European marketing and sales support of the OraTest® product, and (i) to assist in securing the Conformité Européenne (“CE”) Marking for ViziLite® and (ii) to develop and implement marketing plans for ViziLite®. CE Marking is a symbol that indicates a product conforms to the legal requirements of the European Union Directive with respect to health, environment and consumer protection. During fiscal 2005, a nominal amount of OraTest® sales were made in the United Kingdom.

#### **Manufacturing and Supply**

##### *Nutraceuticals*

All Ester-C® and Ester-E® products are manufactured at our Prescott, Arizona location. This 65,000 square foot state of the art facility integrates all manufacturing, quality assurance/quality control, warehousing and distribution for Ester-C® and Ester-E®.

Ascorbic acid is the principal raw material in the formulation and processing of our Ester-C® products and is subject to periodic price fluctuations. To provide price stability, in fiscal year 2004 we obtained a supply of ascorbic acid for a substantial portion of our anticipated requirements through fiscal 2007 by entering into longer term agreements. Prices under these agreements are below our historical average cost, providing cost predictability through the three-year terms of the agreements. Pricing under one of these agreements can fluctuate within a defined range based on foreign currency rates.

The key ingredient in the formulation and processing of Ester-E® is d-alpha tocopherol. In fiscal year 2005, we initiated a strategy to ensure adequate supply and pricing stability by negotiating with suppliers for appropriate supply contracts.

## ***Pharmaceuticals***

### ***ViziLite®***

The ViziLite® product consists of a number of components produced and assembled by different contract manufacturers. For each component, we currently rely on a single source of supply.

### ***Peridex®***

Peridex® is manufactured at a contract facility in Chicago, Illinois. We rely on a single source of supply for the Peridex® product.

### ***IST Products***

All IST products are manufactured at our Antioch, Illinois location.

## ***Biotechnology***

### ***OraTest®***

A contract manufacturing facility in the United Kingdom produces and packages the OraTest® product for sale in that country and other European countries. In order to ensure an available and stable supply of ZTC™, the only pharmaceutical grade tolonium chloride and the active ingredient in the OraTest® product, we established our own manufacturing facility. No other pharmaceutical grade of tolonium chloride is available. The facility, located in Phoenix, Arizona, manufactures ZTC™ under FDA's exacting current Good Manufacturing Practices ("cGMP") standards, providing the pharmaceutical-grade quality required.

## **Competition**

All of the industries in which we sell our products are highly competitive. A number of companies, many of which have greater financial resources, marketing capabilities and research and development capacities than we have, are actively engaged in the development of products that may compete with our products. The nutraceutical, pharmaceutical and biotechnology industries are characterized by extensive and ongoing research efforts that may result in development by other companies of products comparable or superior to any that are now on the market, including those that we sell.

## ***Nutraceuticals***

### ***Ester-C®***

Due to our patent position, we are the sole global producer of calcium ascorbates containing vitamin C metabolites. However, Ester-C® does compete directly with all vitamin C products. Approximately 60% of the world supply of ascorbic acid is produced in China by four manufacturers for export to world markets. The predominant competing vitamin C manufacturer outside Asia is DSM Nutritional Products, Inc., located in Parsippany, New Jersey. We believe that the growing number of health food and vitamin distributors and retailers are increasingly likely to align themselves with producers that offer a wide variety of high quality products, have a loyal customer base, support their brands with strong marketing and advertising programs and provide consistently high levels of customer service, which we believe we provide.

We believe that we compete favorably with other producers of vitamin C because of the positive attributes of our patented Ester-C® products, high customer-order fill rate, strong distribution network, and advertising and promotional support. Our sales trends for Ester-C® products for 2005 were significantly better than those for traditional vitamin C. We believe that our commitment to research demonstrating the benefits of Ester-C® products and our commitment to our marketing partners and consumer focused advertising gives Ester-C® a competitive advantage.

Although the Ester-C® patent expires in 2007, we continue to perform research and development activities to provide additional patent protection for the brand. A patent was issued in 2005 covering a



modified version of our Ester-C® formulation that may extend the patent protection for an improved Ester-C® product beyond 2007. Corresponding patent applications are pending in the United States, Europe and eight additional foreign markets. An International patent application was filed in 2003 based on studies that suggest end-use benefits related to anti-oxidant and environmental oxidant stresses. If issued, the patent may prevent any future manufacturer/marketer of a product containing a mineral ascorbate and a vitamin C metabolite as an imitator Ester-C® type of product (after expiration of the Ester-C® patent in 2007) from marketing the imitator product for the claimed uses. There can be no assurance that any new patents pertaining to the modified Ester-C® product will be issued.

#### *Ester-E®*

Under a licensing arrangement with Vital Health, we utilized Vital Health's patented technology to develop Ester-E® a form of d-alpha tocopheryl phosphate tailored for the dietary supplement marketplace. The first commercial shipments of Ester-E® occurred in May 2004. Ester-E® competes directly with all vitamin E products. The predominant competing vitamin E manufacturers are Archer Daniels Midland ("ADM") and DSM Nutritional Products. As the first branded line extension under our successful "Ester" umbrella, the goal is for Ester-E® to reshape the vitamin E supplement market as Ester-C® has reshaped the vitamin C supplement market, although we cannot offer assurances that we will achieve this goal. Progress towards this goal was made more difficult in fiscal 2005 by the publication of two well publicized studies that questioned the benefit of vitamin E supplementation. Retail sales of vitamin E in the United States have declined by approximately 40% in the food/drug/mass merchandisers distribution channel in the aftermath of these studies and have shown no near term indication of returning to historic levels that prevailed before the publication of these studies.

#### *Pharmaceuticals*

##### *Peridex®*

Peridex® competitors include generic versions and name brands, such as Periogard, made by Colgate Oral Pharmaceuticals. Many of our competitors possess greater financial resources than we have. However, we believe that the reputation of Peridex® as the "gold standard" prescription antibacterial oral rinse within the dental profession and our relationship with Omnii as our distributor to professionals will allow us to continue to compete effectively in the dental healthcare professional marketplace. In addition, we anticipate that new packaging options and new product development activities may allow us to counter inroads made by generic equivalents.

##### *ViziLite®*

ViziLite® is a patented, FDA-cleared device, used to view oral mucosal abnormalities. ViziLite® must contend with altering the conventional method of visual and tactile testing for abnormalities that has previously been the only available methodology for identifying lesions.

#### *IST Products*

The swab products compete with a variety of other product delivery systems, including some that utilize swabs as part of their configuration. The unique IST dry handle swab product provides a clean and convenient product that is patented and is supported by a plastic fusion molding process allowing low cost production of the key molded components.

#### *Biotechnology*

##### *OraTest®*

The OraTest® product has yet to complete its clinical trial program and therefore we cannot market the product in the United States. Because of our focus on the regulatory program, we have not placed emphasis, funding or resources on international markets for the product. However, there are no known competitors to the

OraTest® product in the United States or worldwide. Because the conventional method of using visual examinations by medical personnel to detect oral lesions likely to be cancer is still a widely accepted practice, it may also be viewed as a competitor. ZTC™ and its technology are protected by issued and pending patents. See also Item 1. “Business — Patents and Trademarks.”

## **Licensing**

### *Nutraceuticals*

#### *Ester-E®*

On October 31, 2003, we entered into a license agreement with Vital Health Ltd. (“Vital Health”) that grants us the exclusive rights in the human dietary supplement market in the United States, Canada and Indonesia for certain issued and pending patents, know-how and data pertaining to tocopheryl phosphates. A subsequent agreement entered into on August 4, 2004, extends the terms of the original agreement to give us extensive rights in the animal dietary supplement market in these countries. We also have a right of first refusal for all other international human dietary supplement markets under the agreement. Under the agreement, starting in fiscal 2005 we are required to make royalty payments based on certain levels of sales volume. Additionally, we are subject to minimum annual royalty payment amounts, as defined. The initial term of the license is five years, and we have the right, unilaterally, to extend the term until the expiration of the last of the issued patents covered by the license agreement. Eight patents have been issued in Australia, the United States and/or South Africa, while other applications are pending.

### *Pharmaceuticals*

#### *Peridex®*

On January 30, 2001, we signed a license agreement with Xttrium whereby we granted Xttrium the right to use our technology related to chlorhexidine gluconate, the active ingredient in Peridex®, to produce a private label product for distribution in certain markets. We also have a new agreement that starts in February 2006 and provides us with a royalty of 4% on Xttrium sales of their generic product.

#### *ViziLite®*

In December 2001, we entered into an exclusive agreement with The Trylon Corporation of Torrance, California (“Trylon”) to license the ViziLite® technology. That agreement was modified in October 2003 to reduce the royalties and now provides that we pay Trylon: (i) a 5% royalty on the net sales of the ViziLite® product during the first five years and (ii) a 2.5% royalty on the net sales during the period commencing on the fifth anniversary of the closing date through the tenth anniversary of the closing date after which the royalty payment ends. The license is based on the life of the patents, unless terminated early in accordance with the agreement for certain defaults. This agreement was further modified in March 2004. Under this modification, we have acquired direct ownership for a ViziLite® line extension, the TBlue<sup>630™</sup> marker that was cleared through a 510(k) notification to the FDA. On June 1, 2005, Trylon’s rights, titles and interests under its agreements with us were acquired by Shared Medical Resources, LLC.

### *Biotechnology*

#### *OraTest®*

We have entered into agreements for the manufacture, marketing and distribution of our OraTest® products in several foreign countries. These arrangements are currently inactive as a result of our strategic decision to focus our efforts to obtain the requisite clearances from the FDA to bring our OraTest® product to market in the United States.

Royalty payments would be required should sales of OraTest® product commence in the foreign countries covered by these arrangements.

## **Governmental Regulation**

### ***General***

Our operations are subject to regulation by governmental authorities in the United States and other countries with respect to the testing, approval, manufacture, labeling, marketing, distribution and sale of our products. We devote significant time, effort and expense addressing the extensive government regulations applicable to our business. On an ongoing basis, the FDA reviews the safety and efficacy of marketed pharmaceutical products and monitors labeling, advertising and other matters related to the promotion of such products.

The FDA also regulates the facilities and procedures used to manufacture pharmaceutical products in the United States and the sale of such products in the United States. Such facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with cGMP's (current Good Manufacturing Practices). Compliance with cGMP's requires the dedication of substantial resources and requires significant costs. The FDA periodically inspects both our manufacturing facilities and our contract manufacturing plants and laboratories to review compliance with applicable regulations and procedures. The FDA may request a recall or withdraw product approvals if regulatory standards are not maintained. FDA approval to manufacture a drug is site specific. If an approved manufacturing facility for a particular drug becomes inoperable, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business and results of operations.

In connection with our activities outside the United States, we are also subject to regulatory requirements governing the testing, approval, manufacture, labeling, marketing, distribution and sale of our products, which requirements vary from country to country. Whether or not FDA approval has been obtained for a product, approval of the product by comparable regulatory authorities of foreign countries may need to be obtained prior to marketing the product in those respective countries. 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 United States. No assurance can be given that any clinical studies conducted outside of any country will be accepted by such country and the approval of any pharmaceutical or nutraceutical product in one country does not assure that such product will be approved in another country.

We are also subject to worldwide governmental regulations and controls relating to product safety, efficacy, packaging, labeling and distribution. While not all of the products that we plan to introduce into the market are "new drugs" or "new devices," those fitting the regulatory definitions are subject to a stringent pre-market approval process in most countries. Submission of a substantial amount of preclinical and clinical information prior to market introduction significantly increases the amount of time and related costs incurred for preparing such products for market.

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. These efforts have resulted in, among other things, government policies that encourage the use of generic drugs rather than brand name drugs to reduce drug reimbursement costs. Virtually every state in the United States has a generic substitution law, which permits the dispensing pharmacist to substitute a generic drug, if available, for the prescribed brand name product.

Manufacturing companies, especially those engaged in health care related fields, are subject to a wide range of laws and regulations. Concern for maintaining compliance with federal, state, local and foreign laws and regulations on environmental protection, hazardous waste management, occupational safety and industrial hygiene has also increased substantially. We cannot predict what additional legislation or governmental action, if any, will be enacted or taken with respect to the above matters and what its effect, if any, will be on our consolidated financial position, results of operations or cash flows.

### *Ester-C® and Ester-E®*

Dietary supplements and ingredients in dietary supplements are regulated in the United States by the various states and the FDA. The FDA is the primary governmental regulator of dietary supplements. Under the Dietary Supplement Health & Education Act of 1994 (DSHEA), it is a manufacturer's responsibility to ensure that its products are safe and properly labeled prior to marketing. One of the ways in which a dietary supplement may be adulterated is if it or one of its ingredients presents "a significant or unreasonable risk of illness or injury" when used as directed on the label, or under normal conditions of use (if there are no directions). A dietary supplement that contains a new dietary ingredient (i.e., an ingredient not marketed for dietary supplement use in the United States prior to October 15, 1994) is also considered adulterated unless the dietary supplement contains only ingredients which have been present in the food supply in a form in which the food has not been chemically altered, or for which there is a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe and that the supplement itself that contains the dietary ingredient will be reasonably expected to be safe.

Ester-C® is not considered a new dietary ingredient under the DSHEA because it was marketed before October 15, 1994. Vitamin E also was marketed prior to October 15, 1994. We believe that Ester-E® is not considered to be a new dietary ingredient because its components are not materially different in molecular structure as compared to conventional vitamin E and because it occurs naturally in the food supply.

The FDA also regulates the facilities and procedures used to manufacture dietary supplement products in the United States or for sale in the United States. Such facilities must be registered with the FDA under the Public Health Security and Bioterrorism and Preparedness Act of 2002 and all products made in such facilities must be manufactured in accordance with cGMPs. The cGMPs with which we must comply are the Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food; however, the FDA has proposed GMPs specific to the manufacturing, packing or holding of dietary supplements with which we must comply when finalized. The FDA announced it expects to finalize those regulations by the end of 2005. We have been preparing for implementation of these GMPs since the proposed rule was published and anticipate no material issues with compliance.

The FDA and the FTC work in tandem to regulate the manufacture and sale of dietary supplements and to enforce laws governing fraud, deception and unfair business practices. The FDA has primary responsibility for claims on product labeling, while the FTC has primary responsibility for claims in advertising. All claims for existing and new products are reviewed with regulatory counsel for risk assessment, and substantiation folders are maintained for each claim.

In the European Union, a dietary supplement or ingredient must be on an "approved list" before it can be marketed in member countries, in accordance with the Food Supplements Directive 2002/46/EC. As of July 31, 2003, any ingredient on the market in Europe that is not on the approved list (which includes Ester-C®) must have been submitted with a dossier to support its inclusion no later than July 2005. We submitted our dossier in support of Ester-C® to the European Commission on February 4, 2005. As a result of this submission, we remain eligible to market Ester-C® in key markets where we currently have sales until the earlier of (i) December 31, 2009, or (ii) until the European Commission issues a ruling on our request. Since we are not currently marketing Ester-E® in Europe, a similar application for Ester-E® is not required.

In Canada, new regulations governing natural health products, which include vitamin C and vitamin E, were implemented on January 1, 2004. Products on the market prior to that time will be grandfathered, but products not previously on the market and not included in the Canadian compendium of monographs, such as our Ester-E®, will require submission by our customers of an extensive application to support the safety, efficacy, and quality of finished goods containing Ester-E®. We will be completing a package in fiscal 2006 that our customers can use to submit their finished goods applications.

## *OraTest*<sup>®</sup>

We have not received final FDA approval for OraTest<sup>®</sup> and are conducting a modified phase III clinical program to include in an amended new drug application (“NDA”). We have made a significant financial investment to obtain FDA approval of the OraTest<sup>®</sup> product, develop our manufacturing facility and prepare for the introduction of OraTest<sup>®</sup> in the United States market. There can be no assurance that the FDA will issue a final approval of the OraTest<sup>®</sup> product. See additional discussion below under “Cautionary Factors That May Affect Future Results.”

Although we have received regulatory approval to market the OraTest<sup>®</sup> product in various European countries, we are currently not actively marketing in these countries due to our emphasis on obtaining market approval within the United States.

In January 2005 the Food and Drug Administration cleared the combination product, ViziLite<sup>®</sup> Plus, to be marketed as an adjunct to a ViziLite<sup>®</sup> examination. ViziLite<sup>®</sup> Plus is an oral examination system that contains the ViziLite<sup>®</sup> chemiluminescent device to identify abnormalities in the oral mucosa and a TBlue<sup>630TM</sup> marking device to further evaluate the identified lesions for patients at increased risk for oral cancer. We plan to introduce our ViziLite<sup>®</sup> Plus product at the October 2005 annual meeting of the American Dental Association.

## **Patents and Trademarks**

### *Ester-C*<sup>®</sup>

In 1989, 1990 and 1991, three United States patents were issued in connection with Ester-C<sup>®</sup> nutritional ingredients. All three patents expire in 2007. Twenty-six corresponding foreign patents in countries important to our marketing and distribution strategy have been awarded, with expiration dates ranging from September 2009 in Australia to 2020 in Canada. The first patent covers compositions for administering vitamin C which contain vitamin C metabolites including threonates. The second and third patents cover compositions that include such metabolites and therapeutically active compounds including, but not limited to vitamin C, antibiotics, amino acids, analgesics, and anti-pyretics.

In April, 2005, a patent was issued covering improved vitamin C compositions that may result in additional patent protection of an improved Ester-C<sup>®</sup> product for several additional years. Corresponding patent applications are pending in nine foreign countries. There can be no assurance that any new patents pertaining to the improved Ester-C<sup>®</sup> product will be issued.

Ester-C<sup>®</sup> Topical Concentrate, a stable form of vitamin C that in preliminary studies appears to penetrate the skin to help produce collagen and supporting structures, was awarded a United States patent in March 2001 for “Stable Liquid Mineral Ascorbate Composition and Methods of Manufacturing and Use”, which expires in 2019. Patents have been issued in Australia, New Zealand, Singapore and Taiwan. Corresponding patent applications are pending in ten other foreign countries.

In 2002, we were granted a United States patent for “Methods and Compositions for Potentiating Cancer Chemotherapeutic Agents”, which expires in 2020. This patent is based on cancer chemotherapy research, which showed that two of the vitamin C metabolites found in Ester-C<sup>®</sup> may increase the effects of chemotherapeutic agents. Two related United States patents are pending, along with several corresponding foreign applications, two of which have been granted in China and New Zealand.

We filed an International patent application in 2003 based on studies that suggest end-use benefits related to anti-oxidant and environmental oxidant stresses. If issued, the patent may prevent any future manufacturer/marketer of a product containing a mineral ascorbate and a vitamin C metabolite as an imitator Ester-C<sup>®</sup> type of product (after expiration of the Ester-C<sup>®</sup> patent in 2007) from marketing the imitator product for the claimed uses. We also filed national applications in Malaysia and Taiwan and may file additional national stage applications early in 2006.

Several trademarks have been issued by the United States Patent and Trademark Office (“USPTO”) including the following three major trademarks: (i) the Ester-C<sup>®</sup> trademark (both word and stylized

versions); (ii) the EC® logo trademark; and (iii) the C-Flex® trademark. Related trademarks have been issued in 46 countries with applications pending in several other countries.

#### *Ester-E®*

On October 31, 2003, we entered into a license agreement with Vital Health Ltd. that grants us the exclusive rights in the human dietary supplement market in the United States, Canada and Indonesia for certain issued and pending patents, know-how and data pertaining to tocopheryl phosphates. A subsequent agreement entered into on August 4, 2004, extends the terms of the original agreement to give us extensive rights in the animal dietary supplement market in these countries. We also have a right of first refusal for all other international human dietary supplement markets under the agreement. Under the agreement, starting in fiscal 2005 we are required to make royalty payments based on certain levels of sales volume. Additionally, we are subject to minimum annual royalty payment amounts, as defined. The initial term of the license is five years, and we have the right, unilaterally, to extend the term until the expiration of the last of the issued patents covered by the license agreement. Eight patents have been issued in Australia, The United States and/or South Africa, while other applications are pending. The United States and Australian patents that have been granted cover the "Improved Process for Phosphorylation and Compounds Produced by this Process."

We utilized Vital Health's patented technology to develop Ester-E® tocopheryl phosphates, a form of vitamin E tailored for the dietary supplement marketplace, at our state-of-the-art Arizona laboratories and manufacturing facility. Ester-E® is formed by joining natural d-alpha tocopherol to a phosphate molecule. The patent-protected process is designed to protect the antioxidant potential of vitamin E during absorption, transport, and storage in the body to assist in the delivery of its nutritional benefits when needed.

Preliminary animal studies conducted by Vital Health indicate potential advantages for tocopheryl phosphates in absorption and in the support of cardiovascular health. We initiated a human clinical trial in fiscal 2005 to support the health benefits of Ester-E® and expect to conclude those studies in fiscal 2006.

In September, 2004, the USPTO issued a registration for the Ester-E® trademark. Corresponding trademarks have been issued in 13 foreign countries, with applications pending in several others.

#### *Peridex®*

Peridex® as a brand name has become the "gold standard" within the dental industry for prescription oral rinses in both the United States and Canada. Concurrent with the purchase of the Peridex® brand from Procter & Gamble in November 1997, Zila Pharmaceuticals purchased the trademark rights to Peridex®. Accordingly, Procter & Gamble has assigned the Peridex® trademark to us for each country where it has been previously registered. We recorded our trademark assignment for Peridex® with the USPTO in June 1998 and with the Canadian Registrar of Trademarks in July 1998.

We filed an International patent application for a technology that will cover use of the Peridex® product entitled "Method for Reducing Nosocomial Infections."

#### *ViziLite®*

The December 2001 license agreement with Trylon grants us exclusive and perpetual rights to the ViziLite® technology covered by United States patent numbers 5,179,938 and 5,329,938 issued January 19, 1993, and July 19, 1994, respectively. Together, the patents cover the apparatus and method for endoscopic examination of certain body cavities using a chemiluminescent light source. The license covers reissues and extensions of, along with foreign patents granted and pending based upon, the licensed patents. The ViziLite® trademark was granted registration by the USPTO in December, 2002 and by the European Union in June, 2003.

We have filed an International Application for a technology that will cover use of the ViziLite® chemiluminescent technology entitled "Methods for Detecting Abnormal Epithelial Tissue."

### *IST Products*

With the February 1, 2001 purchase of the assets from National Healthcare Manufacturing Corporation (“NHMC”), we purchased the patent rights related to the “Dry Handle Swab Assembly and Unit.” We were issued a new patent covering an improved version of the swab assembly in June 2002, which will expire in 2021. The USPTO issued a certificate of registration for the Innovative® trademark in July 2002. We filed a trademark application for registration of the IST logo.

### *OraTest®*

When we purchased the shares of CTM Associates, Inc. (“CTM”) in June 1996, we acquired certain technology rights and United States and foreign patent rights related to the OraTest® product. On November 18, 2003, we were granted a patent in the United States covering the method by which our ZTC™ has been shown to detect pre-cancer and cancer cells. The patent is based upon in-vitro studies of the ZTC™ mechanism of action. In December 2004, we were granted a patent in the United States covering all “impurities”/related substances present in ZTC™ at levels equal to or greater than 0.1%. We now have eleven issued United States patents related to ZTC™ and/or the OraTest® product with expiration dates ranging from 2011 to 2020. An additional 59 corresponding foreign patents have been issued, including European patents covering 15 additional countries, and there are pending United States and international applications that would result in coverage of ZTC™ and/or OraTest® related technology by approximately 350 United States and foreign patents. These patents and pending applications cover: (i) the composition of matter for ZTC™; (ii) the process for manufacturing ZTC™; (iii) the mechanism of action, methods and products for using ZTC™ to detect epithelial cancer; and (iv) other compounds that are chemically related to Tolonium Chloride for use in detecting epithelial cancer.

The OraTest® trademark is registered in the United States. We also have trademarks registered in Canada, Israel, Japan, Norway, Switzerland, South Africa and Taiwan, plus 15 European countries that have signed the European Community Trademark treaty. The trademark OraScreen® is registered in Australia, Canada, Ireland, Japan and New Zealand.

### **Employees**

As of July 31, 2005, we had a total of 157 employees, all of which are located in the United States. No employees are represented by a labor union. We believe our relationship with our employees is good.

### **Available Information**

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission (“SEC”) under the Securities Exchange Act of 1934, as amended. The public may read and copy any materials that we file with the SEC at the SEC’s Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet web site that contains reports, proxy and information statements, and other information regarding issuers, including Zila, Inc., that file electronically with the SEC. The public can obtain any documents that we file with the SEC at [www.sec.gov](http://www.sec.gov).

We make available free of charge through our internet web-site, [www.zila.com](http://www.zila.com), our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act as well as Section 16 reports on Forms 3, 4 and 5, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

### **Cautionary Factors That May Affect Future Results and Financial Condition**

This Annual Report on Form 10-K, including the documents incorporated by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the

“Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and are subject to the safe harbors created under the Securities Act and the Exchange Act. Forward-looking statements are identified by words such as “believe,” “anticipate,” “expect,” “estimate,” “intend,” “plan,” “project,” “will,” “may” and variations of such words and similar expressions. In addition, any statements that refer to expectations, projections, plans, objectives, goals, strategies or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements speak only as of the date stated and we do not undertake any obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, even if experience or future events make it clear that any expected results expressed or implied by these forward-looking statements will not be realized. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these expectations may not prove to be correct or we may not achieve the financial results, savings or other benefits anticipated in the forward-looking statements. These forward-looking statements are necessarily estimates reflecting the best judgment of our senior management and involve a number of risks and uncertainties, some of which may be beyond our control, that could cause actual results to differ materially from those suggested by the forward-looking statements. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements are described more fully in the following paragraphs. Our business, financial condition or results of operations could also be adversely affected by other factors besides those listed here. However, these are the risks our management currently believes are material.

***Obtaining regulatory approvals for our products is costly and full of uncertainty.***

The rigorous clinical testing and extensive regulatory approval process mandated by the FDA and equivalent foreign authorities before we can market any new drug, device or product can take a number of years and require the expenditure of substantial resources. Obtaining such approvals and completing such testing is a costly and time-consuming process, and approval may not ultimately be obtained. The length of the FDA regulatory process and review period varies considerably, as does the amount of data required to demonstrate the safety and efficacy of a specific product. If the compounds in testing are modified or optimized or if certain results are obtained, it may extend the testing process. In addition, delays or rejections may be encountered based upon changes in FDA policy during the period of product development and FDA regulatory review of each submitted new drug application, new dietary ingredient notification or product license application. Similar delays may also be encountered in other countries. There can be no assurance that even after such time and expenditures we will obtain regulatory approval for any products we develop.

A marketed product, its manufacturer and its manufacturing facilities are also subject to continual review and periodic inspections, and later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer, potentially including withdrawal of the product from the market which would adversely affect our operations and financial condition.

***We may be unable to obtain FDA approval, or to establish a market, for OraTest® in the United States.***

We are seeking FDA approval for OraTest® and are about to conduct a modified phase III clinical trial to include in an amended NDA. We have made a significant financial investment to obtain FDA approval of the OraTest® product, to build our manufacturing facility and to prepare for the introduction of OraTest® in the United States market. There can be no assurance that the FDA will issue a final approval of the OraTest® product, and the failure of the FDA to approve OraTest® would make it impossible for us to recoup our investment through sales of the OraTest® products in the United States. The failure of the FDA to finally approve the OraTest® product would have a material adverse effect on our results of operations. If regulatory approval is granted, such approval may entail limitations on the indicated uses for which the product may be marketed. Further, even if such regulatory approval is obtained, the FDA may require post-marketing reporting, and may require surveillance programs to monitor the usage or side effects of the product.

If FDA approval of the OraTest® product is received, we must establish a marketing and sales force with technical expertise to market directly to the dental profession or we must obtain the assistance of a company



or a distributor with a sales force. There is no assurance that we will be successful in gaining market acceptance of the OraTest® product.

Based on recent evaluations of the anticipated scope of the regulatory program, we believe that our current cash and cash equivalents, along with cash generated internally from our Nutraceuticals Business Unit, will be adequate to fund the OraTest® clinical study to its completion for submission to the FDA review process. There can be no assurances that these amounts will be adequate to support the future clinical study costs if the trial proceeds at a slower rate than expected, the costs increase beyond current estimates or we are unable to sustain our current level of cash flow from operations. Factors that affect the cost and timing of completion of the regulatory program include but are not limited to: (i) patient enrollment rates; (ii) tumor formation rate within the study population; (iii) compliance with the study protocol and related monitoring; (iv) level of funding throughout the study; and (v) program modifications. No assurances can be made that the FDA will agree to our proposed program modifications, that the regulatory objectives will be achieved or that there will be an enlargement of the post-approval target population or the marketable claims for OraTest®.

At July 31, 2005, we had approximately \$482,000 of OraTest® clinical rinse and swab inventory, ZTC™ drug substance, the active ingredient in the OraTest® product, and its related components. We intend to realize the value of this inventory and drug substance (i) through its consumption during the conduct of the clinical trials, process development, toxicology studies and validation testing of our manufacturing process. The drug substance currently has shelf lives with varying expiration dates. Our periodic testing has indicated that the drug substance is stable and we anticipate being able to extend the expiration dates of the entire drug substance beyond their current expiration dates if our plans are delayed. However, no assurance can be given in this regard.

***We are dependent on a few key products and our growth is dependent on the development of new products.***

Nearly all of our revenues are derived from sales of Ester-C®, Peridex®, and ViziLite®. If any of these major products were to become subject to a problem such as loss of patent protection, unexpected side effects, regulatory proceedings, publicity affecting user confidence, or pressure from competing products, or if a new, more effective treatment should be introduced, the impact on our revenues could be significant. Additionally, we are reliant on third party manufacturers and single suppliers for nearly all of our Peridex® and ViziLite® products, as well as the raw materials for our Ester-C® and Ester-E® products, and any supply problems resulting from regulatory issues applicable to such parties or failures to comply with cGMP could have a material adverse impact on our financial condition.

Our future growth is dependent on new product development. New product initiatives may not be successfully implemented because of many factors, including, but not limited to, difficulty in assimilation, development costs and diversion of management time. There can be no assurance that we will successfully develop and integrate new products into our business that will result in growth and a positive impact on our business, financial condition and results of operation.

A number of factors could impact our plans to commercialize our new products, including, but not limited to, difficulties in the production process, controlling the costs to produce, market and distribute the product on a commercial scale and our ability to do so with favorable gross margins and otherwise on a profitable basis; the inherent difficulty of gaining market acceptance for a new product; competition from larger, more established companies with greater resources; changes in raw material supplies that could result in production delays and higher raw material costs; difficulties in promoting consumer awareness for the new product; adverse publicity regarding the industries in which we market our products; and the cost, timing and ultimate results of human efficacy studies that we undertake.

We can offer no assurances regarding the strength of the patent portfolio underlying any new product and/or technology or whether patents will issue from any pending patent applications related to a new product and/or technology, or if the patents do issue, that any claims allowed will be sufficiently broad to cover the product, technology or production process to effectively limit competition against us is uncertain. Although we

intend to defend our proprietary rights, policing unauthorized use of intellectual property is difficult and any patents that may be issued relating to new products and technology may be challenged, invalidated or circumvented.

***We are dependent on a few key customers.***

In fiscal 2005, approximately 58% of our revenues were generated from three customers. Receivables due from these three customers at July 31, 2005, represent 49% of our accounts receivable. A loss of any of our key customers, a reduction in sales to such key customers for any reason, or a failure to fulfill their financial or other obligations due to us could have a material adverse affect on our business, financial condition and results of operation.

For instance, on March 31, 2004, IST's contract with a major customer expired and was not renewed. This customer represented approximately 80% of IST's net revenues. We were forced to attempt to recoup this lost volume through other new customers. Later in that year, in September 2004, our Board of Directors considered a proposal to divest the net assets of IST, in part, because of the expiration of the contract with the major customer but we were unable to procure an adequate offer for IST. No assurance can be given that any future customer will replace a meaningful portion of the sales volume IST generated before the loss of its principal customer in fiscal 2004.

***We are dependent on our senior management and other key personnel.***

Our ability to operate successfully depends in significant part upon the experience, efforts and abilities of our senior management and other key scientific, technical and managerial personnel. Competition for talented personnel is intense. The loss of services of one or more of our key executives could adversely impact our financial performance and our ability to execute our strategies. Additionally, if we are unable to attract, train, motivate and retain key personnel, our business could be harmed.

***We and our products are subject to regulatory oversight that could substantially interfere with our ability to do business.***

We and our present and future products are subject to risks associated with new federal, state, local or foreign legislation or regulation or adverse determinations by regulators under existing regulations, including the interpretation of and compliance with existing, proposed and future regulatory requirements and dietary supplement and dietary supplement ingredient regulations imposed by the FDA. We are also subject to other governmental authorities such as the Department of Health and Human Services, the Consumer Products Safety Commission, the Department of Justice and the United States Federal Trade Commission with its regulatory authority over, among other items, product safety and efficacy claims made in product labeling and advertising. Individual states, acting through their attorneys general, have become active as well, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. A regulatory determination or development that affects our ability to market or produce one or more of our products could have a material adverse impact on our business, results of operation and financial condition and may include product recalls, denial of approvals and other civil and criminal sanctions.

***We are at risk with respect to product liability claims.***

We could be exposed to possible claims for personal injury resulting from allegedly defective products manufactured by third parties with whom we have entered into manufacturing agreements or by us. We maintain \$6 million in product liability insurance coverage for claims arising from the use of our products and, in most instances, require our manufacturers to carry product liability insurance. While we believe our insurance coverage is adequate, we could be subject to product liability claims in excess of our insurance coverage. In addition, we may be unable to retain our existing coverage in the future. Any significant product liability claims not within the scope of our insurance coverage could have a material adverse effect on us.

***We face significant competition that could adversely affect our results of operation and financial condition.***

The nutraceutical, pharmaceutical and biotechnology industries are highly competitive. A number of companies, many of which have financial resources, marketing capabilities, established relationships, superior experience and operating history and research and development capacities greater than ours, are actively engaged in the development of products similar to the products we produce and market. The pharmaceutical industry is characterized by extensive and ongoing research efforts. Other companies may succeed in developing products superior to those we market. It may be difficult for us to maintain or increase sales volume and market share due to such competition which would adversely affect our results of operations and financial condition. In particular, in the United States, competition with producers of generic products is a major challenge as is the case with Peridex®. The loss of any of our products' patent protection could lead to a significant loss in sales of our products in the United States market.

***If we fail to secure and then enforce patents and other intellectual property rights underlying our technologies, or if the use of our technology is determined to infringe on the intellectual property rights of others, our business could be harmed.***

Our current and future success depends and will depend on a combination of patent, copyright, trademark and trade secret protection, nondisclosure agreements and licensing arrangements to establish and protect our proprietary rights. In addition, we must operate our business without infringing upon the patents and proprietary rights of others, and if needed, obtain appropriate licenses to patents or proprietary rights held by third parties with respect to their technology, both in the United States and in foreign countries. We own and have exclusive licenses to a number of United States and foreign patents and patent applications, and intend to seek additional patent applications, as we deem necessary and appropriate to operate our business. Whether patents will issue from any of our pending applications or, if patents do issue, it is uncertain that any claims allowed will be sufficiently broad to cover our products or to effectively limit competition against us. Furthermore, any patents that may be issued to us may be challenged, invalidated or circumvented. Litigation may result from our use of registered trademarks or common law marks and, if litigation against us were successful, a resulting loss of the right to use a trademark could reduce sales of our products and could result in a significant damage award. Although we intend to defend the proprietary rights, policing unauthorized use of proprietary technology and products is difficult. International operations may be affected by changes in intellectual property legal protections and remedies in foreign countries in which we do business.

Furthermore, if it were ultimately determined that our intellectual property rights are unenforceable, or that our use of our technology infringes on the intellectual property rights of others, we may be required or may desire to obtain licenses to patents and other intellectual property held by third parties to develop, manufacture and market products using our technology. We may not be able to obtain these licenses on commercially reasonable terms, if at all, and any licensed patents or intellectual property that we may obtain may not be valid or enforceable. In addition, the scope of intellectual property protection is subject to scrutiny and challenge by courts and other governmental bodies. Litigation and other proceedings concerning patents and proprietary technologies can be protracted, expensive and distracting to management and companies may sue competitors as a way of delaying the introduction of competitors' products. Any litigation, including any interference proceedings to determine priority of inventions, oppositions to patents in foreign countries or litigation against our partners, may be costly and time-consuming and could significantly harm our business.

Because of the large number of patent filings in our industry, our competitors may have filed applications or been issued patents and may obtain additional patents and proprietary intellectual property rights relating to products or processes competitive with or similar to ours. We cannot be certain that United States or foreign patents do not exist or will not be issued that would harm our ability to commercialize our products and product candidates.

*We require certain raw materials for our manufacturing processes that may only be acquired through limited sources.*

Raw materials essential to our business are generally readily available. However, certain raw materials and components used in the manufacture of nutraceutical and pharmaceutical products are available from limited sources, and in some cases, a single source. Any curtailment in the availability of such raw materials could be accompanied by production delays, and in the case of products, for which only one raw material supplier exists, could result in a material loss of sales. In addition, because raw material sources for pharmaceutical products must generally be approved by regulatory authorities, changes in raw material suppliers could result in production delays, higher raw material costs and loss of sales and customers. Production delays may also be caused by the lack of secondary suppliers. Ascorbic acid is the major raw material in our Ester-C® products and is subject to periodic price fluctuations. During 2003 and early 2004, ascorbic acid prices increased substantially. In fiscal 2004, we executed a strategy to lock in a stable, lower cost ascorbic acid supply for a significant part of our anticipated needs by securing three-year supply contracts from two sources at prices below our historical average cost. If ascorbic acid prices decline sharply, we would be at risk of being committed to purchase ascorbic acid at higher than market prices. Additionally, if our sales were to significantly decline, we would be obligated to purchase ascorbic acid in excess of our needs.

*If we are unable to obtain adequate funds, we may not be able to develop and market our present and potential products.*

As of July 31, 2005 we had cash and cash equivalents of \$12.9 million. We believe that our current cash balances, cash generated from our operations and the availability of cash under our line of credit are sufficient to finance our level of operations, the OraTest® regulatory program, the continued launch of Ester-E® and ViziLite®, and anticipated capital expenditures through the next twelve months. However, the development of our products may require the commitment of substantial resources to conduct the time-consuming research and development, clinical studies and regulatory activities necessary to bring any potential product to market and to establish production, marketing and sales capabilities. In the near future, we may need to raise additional funds for purposes that cannot be quantified and we may seek such additional funding through collaborative arrangements. If we are unable to obtain financing on acceptable terms, or at all, we may be required to (i) delay, scale back or eliminate some or all of our research and product development programs, (ii) to limit the marketing of our products or (iii) to license to third parties the rights to commercialize products or technologies that we would otherwise seek to develop and market ourselves.

On February 6, 2004, we entered into a Credit and Security Agreement (the "Wells Fargo Agreement") with Wells Fargo Business Credit, Inc. ("Wells Fargo") that provides a \$10 million revolving line of credit. Borrowings will bear interest equal to the prime rate. Funds available under the Wells Fargo Agreement are based upon a percentage of the value of eligible receivables and inventory. Obligations under the Wells Fargo Agreement are collateralized by various assets, including, but not limited to trade accounts receivable, inventories, equipment and intangible assets. The parent company, Zila, Inc., guarantees the obligations under the Wells Fargo Agreement.

Under the Wells Fargo Agreement, we are required to maintain net worth, as defined, and to limit capital expenditures to \$3.0 million in fiscal 2006. At July 31, 2005, our net worth, as defined, was \$51.7 million compared to the required amount, of \$39.0 million. Additionally, payment of dividends on our common stock is restricted. The net worth and capital expenditures covenants are established annually as of August 1. The Wells Fargo Agreement contains a provision whereby Wells Fargo can call for immediate repayment of all amounts due under the line upon its sole determination that a "material adverse change" has occurred. As a result of this provision, any borrowings under the Wells Fargo Agreement will be classified as short-term debt. There have been no borrowings under the Wells Fargo Agreement.

If we continue to incur additional operating losses, reduce the value of our net worth, or incur additional debt we may become out of compliance with the covenants and thus have a reduced ability to borrow under the Wells Fargo Agreement.

*In the past, we have experienced volatility in the market price of our common stock and we may experience such volatility in the future.*

The market price of our common stock has fluctuated significantly in the past. We believe that announcements of new products, quarterly fluctuations in the results of operations and other factors, including changes in conditions in general in the industries in which we operate, and developments in regulatory arenas may have caused such fluctuations. Stock markets have experienced extreme price volatility in recent years. This volatility has had a substantial effect on the market prices of securities we issued and other pharmaceutical and health care companies, often for reasons unrelated to the operating performance of the specific companies. In the past, stockholders of other companies have initiated securities class action litigation against such companies following periods of volatility in the market price of the applicable common stock. We anticipate that the market price of our common stock may continue to be volatile. If the market price of our common stock continues to fluctuate and our stockholders initiate this type of litigation, we could incur substantial costs and expenses and such litigation which could divert our management's attention and resources, regardless of the outcome, thereby adversely affecting our business, financial condition and results of operation.

*Our Board of Directors may unilaterally issue Preferred Stock which could dilute our ownership and prevent or delay a change in our control.*

Our Board of Directors has the authority, without any further vote by our stockholders, to issue up to 2,500,000 shares of Preferred Stock in one or more series and to determine the designations, powers, preferences and relative, participating, optional or other rights thereof, including without limitation, the dividend rate (and whether dividends are cumulative), conversion rights, voting rights, rights and terms of redemption, redemption price and liquidation preference. On February 1, 2001, we issued 100,000 shares of our Series B Convertible Preferred Stock related to the IST acquisition. As of July 31, 2005, all of these shares remained outstanding.

*If we use environmentally hazardous materials in a manner that causes injury, we may be liable for damages.*

We are subject to federal, state and local laws and regulations governing the use, generation, manufacture, storage, discharge, handling and disposal of certain materials and wastes used in our operations, some of which are classified as "hazardous." We could be required to incur significant costs to comply with environmental laws and regulations as our research activities are increased, and current or future environmental laws and regulations could adversely affect our operations, business and future profitability. Although we believe that our safety procedures for handling and disposing materials comply with such laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

*We have, in the past, received minor deficiencies from regulatory agencies related to our manufacturing facilities.*

The FDA, OSHA and other regulatory agencies periodically inspect our manufacturing facilities and certain facilities of our suppliers. In the past, such inspections resulted in the identification of certain minor deficiencies in the standards we are required to maintain by such regulatory agencies. We developed and implemented action plans to remedy the deficiencies, however, there can be no assurance that such deficiencies will be remedied to the satisfaction of the applicable regulatory body. In the event that we are unable to remedy such deficiencies, our product supply could be affected as a result of plant shutdown, product recall or other similar regulatory actions, which would likely have an adverse affect on our business, financial condition and results of operation.

## **Item 2. Properties**

### ***Corporate Headquarters***

We lease our 16,000 square foot corporate headquarters located at 5227 North Seventh Street, Phoenix, Arizona 85014-2800. Monthly lease payments are currently \$13,900 increasing to \$14,800 in the final year of the lease. The lease has two five-year renewal options with monthly rent beginning at \$15,100 and increasing annually to \$18,000 at the end of the second five-year renewal option.

### ***Manufacturing Facilities***

We lease 15,500 square feet for a manufacturing facility and laboratory in Phoenix, Arizona. This facility produces ZTC™, which is the active ingredient in the OraTest® product as well as provides technical support and testing for our other pharmaceutical products. The facility is leased under a 56-month agreement, which expires December 31, 2010. Monthly lease payments are: \$11,900 through December 31, 2005; \$12,300 through August 31, 2007; \$13,000 through April 30, 2009; and \$13,800 through December 31, 2010. Together with our laboratory facilities, we believe that our current manufacturers are capable of performing all necessary production for us. See "Item 1. Business — Manufacturing and Supply."

The Nutraceuticals Business Unit owns five acres and occupies a 65,000 square foot facility located at 6735 Inter-Cal Way, Prescott, Arizona 86301. The building features production, laboratory, packaging, storage and shipping areas, as well as a controlled environment, and was financed from Yavapai County Industrial Development Authority Bond proceeds. The construction and move to the facility was completed in the fall of 2000.

IST leases 14,400 square feet for a manufacturing facility in Antioch, Illinois for the manufacture and distribution of dry handled swab products and probe covers. The facility is leased under a seven-year agreement, which expires January 31, 2008. The lease has an option to renew for an additional three years. Monthly lease payments are \$5,700.

## **Item 3. Legal Proceedings**

Except as described below, we are not a party to any pending legal proceedings other than claims that arise in the conduct of our business. While we currently believe that the ultimate outcome of these proceedings will not have a material adverse effect on our consolidated financial condition or results of operations, litigation is subject to inherent uncertainties. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on our net income in the period in which a ruling occurs. Our estimate of the potential impact of the following legal proceedings on our financial position and our results of operation could change in the future.

In connection with the acquisition of patent rights in 1980, we agreed to pay to Dr. James E. Tinnell ("Tinnell"), the inventor of one of our former treatment compositions, a royalty of 5% of gross sales of the invention disclosed in his then pending patent application. In September 2000, we notified Tinnell that we would no longer pay such royalties because the obligations ceased in August 1998 when the related product patents expired and we requested reimbursement of royalties paid since August 1998. We then filed suit in the Federal District Court requesting a declaratory judgment that we had no royalty obligations to Tinnell and requested judgment for the overpaid royalties. On April 22, 2004, the Court, in part, ruled in our favor, stating that our royalty obligations to Tinnell ceased in August 1998, however, our request for reimbursement of overpaid royalties was dismissed. Tinnell filed a notice of appeal and we have filed a notice of cross-appeal. Briefs have been filed by both parties with the Ninth Circuit Court of Appeals.

In early December 2004, we became aware of a purported class action lawsuit filed in the Superior Court of the State of Arizona for Maricopa County against Matrixx Initiatives, Inc. and a number of other defendants, including us and IST. The lawsuit alleges that the Zicam Cold Remedy Product manufactured by Matrixx Initiatives, Inc., a former customer of IST, caused damage to the sense of smell and/or taste of the plaintiffs. Other defendants in the lawsuit include manufacturers and retailers. IST had produced swabs and containers for the Zicam Cold Remedy Product for a limited period that ended in March 2004. We and IST

have not yet been served with this lawsuit; however, if we and IST are made parties to the lawsuit, we will contest it vigorously. We believe that the plaintiffs' claims with respect to us and IST are without merit.

On January 25, 2005, Ronald Fugate, a former employee, filed a lawsuit in the Superior Court of the State of Arizona alleging wrongful termination in the case captioned Ronald Fugate v. Zila, Inc., et al CV2005-001218. A confidential mediated settlement was reached in July 2005.

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

We did not submit any matter to a vote of our security holders during the fourth quarter of the fiscal year covered by this report.

**PART II**

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

Information regarding the market for our Common Stock and related stockholder matters is set forth below. The following table sets forth, for the fiscal periods shown, the high and low quotations in dollars per share for our Common Stock as reported by the National Association of Securities Dealers Automated Quotation System ("NASDAQ").

	<u>High</u>	<u>Low</u>
<b>Fiscal Year Ended July 31, 2005</b>		
First quarter .....	\$4.59	\$3.31
Second quarter .....	5.00	3.42
Third quarter .....	5.09	2.99
Fourth quarter .....	3.80	2.55
<b>Fiscal Year Ended July 31, 2004</b>		
First quarter .....	\$4.01	\$2.43
Second quarter .....	4.97	3.50
Third quarter .....	5.53	3.87
Fourth quarter .....	5.28	3.81

The number of stockholders of record of the common stock as of July 31, 2005 and September 30, 2005 were approximately 2,752 and 2,738, respectively.

We have not paid dividends on our common stock. The policy of our Board of Directors has been to retain earnings to finance the growth and development of our business. Payment of cash dividends is restricted by the terms of our credit agreements with Wells Fargo Business Credit, Inc.

**Preferred Stock**

On February 1, 2001, as part of the IST acquisition, we issued 100,000 shares of Series B Convertible Preferred Stock ("Preferred Stock") to National Healthcare Manufacturing Corporation for the patent rights and the Antioch, Illinois manufacturing operations for swab products. The Preferred Stock is convertible into shares of our common stock at any time at a conversion ratio of one to one. The holders of the Preferred Stock are entitled to receive cumulative quarterly dividends at a rate of \$0.0975 per share per fiscal quarter, payable in arrears. Holders of the Preferred Stock have no voting rights except as required by applicable law. We paid the holders of the preferred stock dividends of \$68,250 during fiscal 2005, \$19,500 during 2004, \$49,000 during 2003 and \$29,000 during 2002. Accumulated accrued dividends are \$9,750 as of July 31, 2005. No dividends were paid in 2001. The shares of Preferred Stock were issued pursuant to the exemption set forth in Section 4(2) of the Securities Act. There is no established public trading market for the Preferred Stock. As of July 31, 2005, there are 100,000 shares of our Preferred Stock outstanding.

## **Restricted Stock — Rule 144**

On December 4, 2001, we acquired the world wide marketing and distribution rights (excluding the Pacific Rim) for the FDA cleared ViziLite®chemiluminescent light technology from Trylon. In connection with the transaction, we issued 2,000,000 shares of restricted common stock, of which 1,625,000 shares were delivered to Trylon and 375,000 shares were placed into escrow. Thereafter, we conducted a mediation with Trylon and entered into a mediation settlement on October 15, 2003. This settlement addressed the contractual restrictions affecting 875,000 of the 1,625,000 shares originally delivered to Trylon and the escrow restrictions on the 375,000 shares held in escrow. We further modified the agreements with Trylon on March 26, 2004 and July 31, 2004. Those modifications also addressed the contractual and escrow stock restrictions. As a result of the mediation settlement and the other modifications, on March 26, 2004 we agreed to lift contractual restrictions on 312,500 of the 875,000 shares referred to above. We agreed to lift contractual restrictions on another 312,500 of the 875,000 shares referred to above on July 31, 2004. Contractual restrictions on the remaining 250,000 shares were removed on January 31, 2005 upon obtaining of the required governmental approvals relating to a product development milestone. On June 30, 2004, Trylon forfeited all of its rights to the 375,000 shares subject to the escrow restrictions and the escrow agent returned these shares to us. All 1,625,000 shares issued to Trylon were issued pursuant to the exemption set forth in Section 4(2) of the Securities Act and are restricted within the meaning of Rule 144 under the Securities Act. All of those shares may be eligible for sale subject to the holding period and other requirements of that Rule.

## **Warrants**

On March 14, 2003, we issued warrants to purchase 104,000 shares of our common stock to members of our Medical Advisory Board. The exercise price is \$0.98 per share. The warrants were issued pursuant to the exemption set forth in Section 4(2) of the Securities Act.

We entered into an agreement with a financial advisor during fiscal 2002 to perform consulting services. Under the agreement, we are committed to issue warrants to purchase 30,000 shares of our common stock for \$0.74 for 24,000 shares and \$4.00 per share for 6,000 shares. At July 31, 2003, \$28,000 was included in accrued liabilities representing the fair value of the warrants expected to be issued. The warrants were effective as of July 24, 2002 and subsequently issued on November 6, 2003. The warrants were issued pursuant to the exemption set forth in Section 4(2) of the Securities Act.

On December 21, 2000, we issued a warrant to purchase 15,000 shares of our common stock to a financial advisor. The warrant was issued pursuant to the terms of a consulting agreement and 7,500 of the shares underlying the warrant have an exercise price of \$4.00 per share and 7,500 of the shares have an exercise price of \$5.00 per share and the warrant expires on December 21, 2010. The warrant was issued pursuant to the exemption set forth in Section 4(2) of the Securities Act.

On March 23, 2000, we issued a warrant to purchase 10,000 shares of our common stock to a financial advisor. The warrant was issued pursuant to the terms of an engagement agreement, and the exercise price is \$4.906 per share. The warrant was issued pursuant to the exemption set forth in Section 4(2) of the Securities Act.

## **Issuer Repurchase of Equity Securities**

We did not repurchase any of our equity securities pursuant to our Stock Repurchase Program during fiscal 2005.



## Item 6. Selected Financial Data

The following tables summarize selected financial information derived from our audited financial statements. The information set forth below is not necessarily indicative of results of future operations and should be read in conjunction with our Consolidated Financial Statements and related Notes and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Form 10-K. (Dollars in thousands, except per share amounts.)

<u>Statement of Operations Data:</u>	<u>Fiscal Years Ended July 31,</u>				
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>
Net revenues .....	\$44,325	\$41,405	\$39,210	\$ 24,521	\$ 19,163
Net income (loss) from continuing operations before accounting change ..	(9,030)	(4,375)	11,611(1)	(13,519)	(10,219)
Net income (loss) attributable to common shareholders .....	1,060	(4,376)	7,246(2)	(12,069)	(6,390)
Basic and diluted net income (loss) per share attributable to common shareholders .....	\$ 0.02	\$ (0.10)	\$ 0.16	\$ (0.27)	\$ (0.15)

<u>Balance Sheet Data:</u>	<u>At July 31,</u>				
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>
Current assets .....	\$32,639	\$30,123	\$35,326	\$20,810	\$34,090
Total assets .....	65,418	62,109	69,020	57,361	75,603
Current liabilities .....	9,815	7,581	11,519	7,427	15,803
Long-term debt .....	3,328	3,650	3,728	3,610	4,153
Total liabilities .....	13,696	11,880	15,272	11,038	19,956
Series B convertible preferred stock .....	463	463	463	463	463
Total shareholders' equity .....	51,722	50,228	53,748	46,323	55,646

- (1) Includes \$14.8 million contract settlement gain from our former contract research organization (see Note 6 of Notes to Consolidated Financial Statements).
- (2) Includes adoption of SFAS No. 142, "Goodwill and Other Intangibles Assets," in which we recorded a charge of \$4.1 million reported under the caption "Cumulative effect of accounting change" on our Consolidated Statements of Operations.

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

### Overview

You should read the following discussion and analysis together with the financial data in the section labeled "Selected Financial Data" and with our audited Consolidated Financial Statements and Notes thereto.

We are an innovator in preventive healthcare technologies and nutraceutical, pharmaceutical and biotechnology products, focusing on enhanced body defense and the detection of pre-disease states. Our business is organized into the following Business Units:

- Zila Nutraceuticals, manufacturer and marketer of *Advanced Protection Ester-C*® and Ester-E®, proprietary, branded, highly effective forms of vitamins C and E.
- Zila Pharmaceuticals, manufacturer and marketer of superior products to promote oral health and prevent oral disease, including the ViziLite® chemiluminescent light for illumination of oral mucosal abnormalities and its adjunct product ViziLite® Plus with T-Blue<sup>630™</sup>, Peridex® prescription periodontal rinse, and the plastic molded products of Zila Swab Technologies, Inc. ("IST").

- Zila Biotechnology, a research, development and licensing business specializing in pre-cancer/cancer detection through its patented ZTC™ and OraTest® technologies.

Our strategic approach to the management of our business units is driven by our commitment to grow our Nutraceutical and Pharmaceutical businesses while we successfully complete the OraTest® regulatory program. To that end, we are investing more aggressively in our core nutraceutical and pharmaceutical products to drive greater profitability and the required cash flows to fund the research and development efforts being managed by the Biotechnology Business Unit as well as our Ester-E® and ViziLite® Plus product launches. In doing so, our corporate goal is to manage the entire portfolio of business units in a manner such that over the course of a given fiscal year, our Earnings before Interest, Taxes, Depreciation and Amortization (“EBITDA”) and our management of working capital would provide an acceptable level of cash availability to fund the completion of the OraTest® regulatory program. We plan to continue with this goal while we seek to obtain the requisite clearances from the United States Food and Drug Administration (“FDA”) to bring our OraTest® product to market in the United States. Market forces, such as the market acceptance of new products such as ViziLite® and our new ViziLite® Plus and Ester-E® products, and other such variables and risk factors, can and do influence our ability to accomplish this goal. Our level of research and development activities, and the associated costs, will likely trend above our historical levels as we accelerate our efforts to advance our OraTest® regulatory program. Accordingly, unless our other business units produce a sufficient, higher level of EBITDA to offset these additional costs, we will operate on a negative EBITDA basis during this period. We believe that our current cash balances, cash generated from our operations, net proceeds from our investing activities and the availability of cash under our line of credit are sufficient to finance our level of operations, the OraTest® regulatory program, the continuation of the launches of ViziLite® and Ester-E® and anticipated capital expenditures. See page 15 for further discussion of the risk factors that we face in our businesses.

In connection with our dialogue with the FDA, we proposed modifications to the current OraTest® regulatory program aimed at reducing its overall duration and total cost. It is our goal to include the evaluation of OraTest® in the accurate identification of severe dysplasia (pre-cancer) in addition to carcinoma in-situ and invasive carcinoma (cancer) as acceptable clinical endpoints in the modified program. It is also our objective to collect data in a population of individuals at high risk of oral cancer (primary cancer screening) while still reducing the cost and duration of the current regulatory program. If the clinical objectives are achieved, it may also permit enlargement of the post-approval target population and the marketable claims for OraTest®.

The primary modification incorporated into the proposed regulatory program is the inclusion of severe dysplasia as a primary endpoint of the trial. Additionally, certain elements of the amended program would allow for a substantial reduction in patient visits and the cost and duration of the program. We anticipate that patient enrollment in the Phase III regulatory program will begin by the end of calendar 2005. We further believe that we can complete the study within twelve months of enrolling the first patients, although no assurances can be given in either regard. The trial is expected to require fewer than 4,000 patients who generally undergo a single visit. Upon completion of the clinical trial and assuming that the clinical endpoints have been achieved, we estimate that it will require two to three months to prepare the new drug application for submission to the FDA. From there it is difficult to predict how long it may take the FDA to review and comment upon the application.

In June 2005, we completed the sale of the Zilactin® brand of over-the-counter products to a third party. Cash proceeds of the sale totaled approximately \$11.0 million. The financial statements included herein reflect the treatment of the financial results of the Zilactin® line as discontinued operations. (See Note 3 of the Notes to Consolidated Financial Statements for further discussion.)

We have a human clinical trial currently underway and a second trial protocol being developed in support of our Ester-E® product. The U.S. market for single supplement forms of vitamin E was negatively impacted by research work that was published during fiscal 2005 that, in some cases, questioned the benefit of vitamin E supplementation and, in other cases, actually suggested that vitamin E supplementation might be harmful beyond certain dosage levels. We do not believe that the conclusions of these studies are valid as they relate to

vitamin E supplementation by healthy individuals or to Ester-E® specifically. The launch of our Ester-E® product was made more difficult by these publications. The clinical work that we are doing in support of Ester-E® is directed to differentiating Ester-E® from other forms of vitamin E that are currently available, as well as seeking to demonstrate the safety and other healthful properties of the product.

## Results of Operations

### *Fiscal Year Ended July 31, 2005 Compared to Fiscal Year Ended July 31, 2004*

The following tables summarize our results of operations and related statistical information for the fiscal years ended July 31, 2005 and 2004 (dollars in thousands):

	Fiscal Years Ended July 31,				
	2005	Percent of Net Revenues	2004	Percent of Net Revenues	% Change
Net revenues .....	\$44,325	100%	\$41,405	100%	7
Cost of products sold .....	15,385	35	16,120	39	(5)
Gross profit .....	28,940	65	25,285	61	14
Operating expenses:					
Marketing & selling .....	15,939	36	9,552	23	67
General & administrative .....	11,538	26	11,149	27	3
Severance and related charges .....	192	—	350	1	(45)
Other operating costs .....	296	1	—	—	—
Research & development .....	7,181	16	5,933	14	21
Impairment of assets .....	—	—	289	1	(100)
Depreciation & amortization .....	2,688	6	2,483	6	8
	37,834	85	29,756	72	27
Loss from operations .....	(8,894)	(20)	(4,471)	(11)	99
Other income (expense), net .....	(128)	—	99	—	(229)
Loss from continuing operations before income taxes and accounting change ...	<u>\$ (9,022)</u>	<u>(20)</u>	<u>\$ (4,372)</u>	<u>(11)</u>	106

### *Consolidated*

Net revenues increased 7% to \$44.3 million for fiscal 2005, compared to revenues of \$41.4 million for fiscal 2004. Without the effect of IST (see the Pharmaceuticals Business Unit section below), consolidated net revenues increased 19% compared to the prior year. We achieved growth in net revenues during the current fiscal year in both our nutraceutical and core pharmaceutical product lines over the prior year. For fiscal 2005, net revenues of the Nutraceuticals Business Unit increased 19% compared to the prior year. Net revenues for the core Pharmaceuticals Business Unit, without the effect of IST, increased 18% compared to the prior year.

Gross profit as a percentage of net revenues increased to 65% for fiscal 2005 compared to 61% for the prior year. The primary factor contributing to this improvement was the reduced cost of ascorbic acid, the major raw material in our Ester-C® products.

Marketing and selling expenses as a percentage of net revenues increased to 36% for fiscal 2005 compared to 23%, for the prior year. Increased spending for brand and media advertising support for Ester-C®, the launch of Ester-E® and increased marketing and selling expenditures for ViziLite® were the primary reasons for these increases.

General and administrative expenses were \$11.5 million, or 26% of net revenues, for fiscal 2005, and \$11.1 million, or 27% of net revenues, for fiscal 2004. The increased G&A expenses were driven primarily by professional fees incurred at the corporate level in connection with our Sarbanes-Oxley Section 404 internal control compliance efforts. We incurred \$789,000 for fiscal 2005 related to Sarbanes-Oxley 404 compliance. Offsetting the increase described above were reductions in expenses resulting from IST's downsizing of its operations after the loss of its major customer and from overall cost reduction measures throughout all of our business units.

Severance and related charges were \$192,000 for fiscal 2005, and \$350,000 for fiscal 2004. These costs decreased as we proceeded under our personnel reorganization plan.

Other operating costs were \$296,000 for fiscal 2005, or 1% of net revenues. These costs were incurred at IST and represent engineering and consulting costs to upgrade IST's manufacturing and quality control procedures.

Research and development expenses were \$7.2 million, or 16% of net revenues, for fiscal 2005, and \$5.9 million, or 14% of net revenues, for fiscal 2004. The increase in research and development expenses is due primarily to costs for our OraTest® regulatory program and for the re-commissioning our ZTC™ manufacturing facility.

An impairment charge of \$289,000 was recorded in the Pharmaceuticals Business Unit in the fourth quarter of fiscal 2004 for IST related to the write-down of fixtures, equipment, patents and trademarks. In March 2004, our Board of Directors authorized the divestiture of the net assets of IST, our plastic molded products manufacturing subsidiary, in order to focus on our core business operations. In September 2004, we reversed the divestiture decision and withdrew IST from the market. No acceptable purchase offer was produced by the effort to market IST. Based on the results of the offer process and in accordance with the requirements of SFAS No. 144, we recognized a non-cash impairment charge to give effect to our revised estimate of the fair value of IST.

Depreciation and amortization expense increased \$205,000, or 8%, to \$2.7 million for fiscal 2005. The increase in depreciation expense resulted from the additions of property and equipment for the Nutraceuticals Business Unit production room expansion, and the Biotechnology Business Unit manufacturing facility re-commissioning project. Increased amortization resulted from additions of patents and trademarks in the Nutraceuticals and Pharmaceuticals Business Units.

Other expense for fiscal 2005 was \$128,000 compared to other income of \$99,000 in the prior year. A reduction in short-term borrowing over the prior year period resulted in decreased interest expense. The prior year includes a \$470,000 gain on the sale and leaseback of our Corporate Headquarters facility on January 30, 2004.

***Nutraceuticals***

Selected financial information for the Nutraceuticals Business Unit follows for the fiscal years ended July 31, 2005 and 2004 (dollars in thousands):

	Fiscal Years Ended July 31,		
	2005	2004	% Change
Net revenues . . . . .	\$38,471	\$32,432	19
Gross profit . . . . .	25,994	20,286	28
Gross profit % . . . . .	68%	63%	
Income from operations before income taxes . . . . .	9,022	8,300	9

A number of factors have influenced the revenue, profitability and other financial performance of the Nutraceuticals Business Unit in fiscal 2005, including:

- Growing consumer awareness and trial of Ester-C® in response to increased media and promotion investment and improved advertising methods;
- Improved gross profits through purchase of ascorbic acid under supply agreements that provided a substantial portion of our annual requirements at prices equivalent to historical averages, providing cost predictability for our Ester-C® products;
- The commercial introduction of our Ester-E® tocopheryl phosphates, an enhanced form of natural vitamin E and the first line extension under our successful "Ester" umbrella of products, was made much more difficult and ultimately unprofitable to date by unprecedented and unexpected negative publicity regarding vitamin E;
- Increased capacity and efficiency through upgrading our Ester-C® production facility in Prescott, Arizona;
- Consolidation amongst our customer base that has increased the percentage of our total revenues that is attributable to one of our largest customers, NBTY, Inc.

Net revenues for the Nutraceuticals Business Unit for fiscal 2005 increased 19% over the prior year. This growth was primarily in domestic sales for Ester-C® and was driven principally by increased radio and television advertising support for our Ester-C® and Ester-E® products made under our continuing strategy of brand development. Due to the impact of negative publicity regarding vitamin E, our sales of Ester-E® were less than anticipated.

Gross profit as a percentage of net revenues increased to 68% for fiscal 2005 compared to 63% for the prior year. The primary factor contributing to this improvement was the reduced cost of ascorbic acid, the major raw material in our Ester-C® products. Due to the execution in the fourth quarter of fiscal 2004 of certain supply agreements for the purchase of ascorbic acid, the rate of improvement in the gross margin should not be expected to extend beyond fiscal 2005 but rather gross profit for the Nutraceuticals Business Unit should be expected to stabilize and be sustained in the high 60's as a percent of net revenues.

Income from operations before taxes for the Nutraceuticals Business Unit for fiscal 2005, was \$9.0 million, increasing by 9% over the prior year. The primary factor in this increase was gross margin improvement resulting from reductions in the cost of ascorbic acid under our lower cost extended supply agreements and from cost reduction measures in general and administrative expenses. Offsetting these improvements, spending for brand and media advertising support for Ester-C® and for the launch of Ester-E® increased 49% over the prior year.

## Pharmaceuticals

Selected financial information for the Pharmaceuticals Business Unit follows for the fiscal years ended July 31, 2005 and 2004 (dollars in thousands):

	Fiscal Years Ended July 31,		
	2005	2004	% Change
Net revenues:			
Core Pharmaceuticals products .....	\$ 5,010	\$4,248	18
IST* .....	<u>836</u>	<u>4,723</u>	(82)
Total net revenues .....	5,846	8,971	(35)
Gross profit:			
Core Pharmaceuticals gross profit .....	3,228	2,898	11
Gross profit % .....	64%	68%	
IST* .....	(276)	2,088	(113)
Gross profit % .....	(33)%	44%	
Total gross profit .....	2,952	4,986	(41)
Total gross profit % .....	51%	56%	
Operating loss before income taxes:			
Core Pharmaceuticals .....	(857)	(566)	51
IST* .....	<u>(1,757)</u>	<u>(199)</u>	783
Total operating loss before income taxes .....	(2,614)	(765)	242

\* *Net of intercompany eliminations*

The Pharmaceuticals Business Unit has more complex operations than our Nutraceuticals Business Unit since it competes in multiple markets (direct to dental professionals, sales to dental distributors via independent representatives and swab applications) with four distribution methods (wholesalers, master distributor arrangements, independent sales representatives and direct sales team). The key factors influencing the Pharmaceuticals Business Unit's financial performance and operations during fiscal 2005 include:

- A continued product rollout of ViziLite® with emphasis in key markets that resulted in improving sales trends;
- Strengthening the position of Peridex® in the direct to dental market via competitive new advertising and new packaging forms;
- Increased marketing and selling investment to increase Peridex® brand value and to support the ViziLite® rollout;
- Loss of a major IST customer late in fiscal 2004 which continued to negatively impacted net revenues, gross profit and operating results in fiscal 2005.

Net revenues for fiscal 2005 for the core products in the Pharmaceuticals Business Unit (without IST) increased 18% to \$5.0 million compared to \$4.2 million for fiscal 2004. This increase resulted primarily from gains in net revenues from ViziLite® driven largely by sales and marketing efforts. The growth in ViziLite® net revenues continues through our strategy of educating the dental professional and broadening distribution channels. Net revenues for our Peridex® product decreased between years primarily as a result of softer United States wholesaler demand. Net revenues for the Pharmaceuticals Business Unit include the net revenues of IST. Our contract with IST's major customer expired on March 31, 2004, and our net revenues from IST declined significantly during the balance of fiscal 2004. IST is actively pursuing new customer arrangements to mitigate the loss of net revenues. There can be no assurances that it will be successful in this regard.

Gross profit as a percentage of net revenues for the core products in the Pharmaceuticals Business Unit (without IST) decreased to 64% during fiscal 2005 from 68% for fiscal 2004, primarily due to the reduction in higher margin sales to wholesalers for Peridex®. The decrease in the Peridex® gross profit percent offset improvements in ViziLite® in fiscal 2005. In the prior year, higher cost of product for ViziLite® resulted from its product launch. IST's negative gross margin percentage resulted from excess capacity costs caused by the loss of its major customer.

Operating loss before incomes taxes for the Pharmaceuticals Business unit was \$2.6 million for fiscal 2005 compared to \$765,000 for the prior fiscal year. An impairment charge of \$289,000 was recorded in the fourth quarter of fiscal 2004 related to IST. The increased net loss resulted primarily from (i) IST's loss of a major customer; (ii) costs incurred for engineering and consulting to upgrade IST's manufacturing and quality control procedures; and (iii) increased selling and marketing expenses for the core product lines in the Pharmaceuticals Business unit.

### *Biotechnology*

Selected financial information for the Biotechnology Business Unit follows for the fiscal years ended July 31, 2005 and 2004 (dollars in thousands):

	Fiscal Years Ended July 31,		
	2005	2004	% Change
Net revenues . . . . .	\$ 8	\$ 2	300
Research and development . . . . .	6,696	5,476	22
Loss from continuing operations before income taxes . . . . .	(8,694)	(7,195)	21

A number of factors have influenced the financial results for the Biotechnology Business Unit in 2005, including:

- Increased spending for the OraTest® product regulatory program;
- Continued development of a commercialization strategy for the OraTest® product;
- Approval of modifications to the current OraTest® regulatory program submitted to the FDA and aimed at reducing the program's overall duration and total cost;
- Re-commissioning of our ZTC™ manufacturing facility to support our regulatory program and the production of ViziLite® Plus with TBlue<sup>630™</sup>, the first commercialized use of our ZTC™ technology;
- Renegotiation of the General Services Agreement with Quintiles Transnational Corp. ("Quintiles"), our contract research organization, to support the modifications to our regulatory program;
- Expanded use of our Medical Advisory Board, whose members are some of the world's leading researchers studying cancers located in the head and neck, to assist in development of our regulatory strategy to reduce the cost and duration of our current regulatory program and in development of our product commercialization strategy; and
- Evaluation of other ZTC™ pre-cancer and cancer detection applications.

Revenues from sales of the OraTest® product were generated in the United Kingdom and were nominal during fiscal 2005 and 2004, as we focused on obtaining FDA approval in the United States.

The loss from operations before income taxes for the Biotechnology Business Unit was \$8.7 million for fiscal 2005, a 21% increase over the \$7.2 million for fiscal 2004. This was driven by an increase of \$1.2 million in regulatory program expenses related to the OraTest® product.

## Results of Operations

### *Fiscal Year Ended July 31, 2004 Compared to Fiscal Year Ended July 31, 2003*

The following tables summarize our results of operations and related statistical information for the fiscal years ended July 31, 2004 and 2003 (dollars in thousands):

	Fiscal Years Ended July 31,				
	2004	Percent of Net Revenues	2003	Percent of Net Revenues	% Change
Net revenues .....	\$41,405	100%	\$39,210	100%	6
Cost of products sold .....	16,120	39	16,772	43	(4)
Gross profit .....	25,285	61	22,438	57	13
Operating Expenses:					
Marketing & selling .....	9,552	23	7,225	18	32
General & administrative .....	11,149	27	10,363	26	8
Severance and related charges .....	350	1	1,322	3	(74)
Research & development .....	5,933	14	4,137	11	43
Impairment of assets .....	289	1	141	1	105
Depreciation & amortization .....	2,483	6	2,346	6	6
	29,756	72	25,534	65	17
Loss from operations .....	(4,471)	(11)	(3,096)	(8)	44
Contract settlement gain, net of related expenses .....	—	—	14,844	38	(100)
Other income (expense), net .....	99	—	51	—	94
Income (loss) from continuing operations before income taxes and accounting change .....	<u>\$(4,372)</u>	<u>(11)</u>	<u>\$11,799</u>	<u>30</u>	<u>(137)</u>

### *Consolidated*

Net revenues increased 6% to \$41.4 million for fiscal 2004, compared to revenues of \$39.2 million for fiscal 2003. The increase is due to a 10% net revenue increase in the Nutraceuticals Business Unit offset by an 8% decrease in the Pharmaceuticals Business Unit. When the net revenues of the discontinued Saw Palmetto oil product line are removed from both years, net revenues increased 24% at the Nutraceuticals Business Unit and 15% for the total Company. Increased spending in advertising and promotional programs and the commercial introduction of our new Ester-E® product contributed to the sales gains.

Gross profit as a percentage of net revenues for fiscal 2004 increased to 61% from 57%. This increase is due primarily to a March 2003 selling price increase at IST and the effect of sales of the low margin saw palmetto products in the prior year in our Nutraceuticals Business Unit as we sought to liquidate our remaining inventories. These improvements in gross profit were offset by an increase in the cost of products for our Ester-C® caused primarily by a \$3.0 million increase in the cost of ascorbic acid, principally in the first half of fiscal 2004. Also, to a lesser extent, the improvements in gross profit were offset by increased product costs related to promotional activities and increased manufacturing costs in the Pharmaceuticals Business Unit.

Marketing and selling expenses as a percentage of net revenues for fiscal 2004 increased to 23% from 18%. This increase was primarily due to heavy brand and media advertising support for the Nutraceuticals Business Unit product, Ester-C®, and increased marketing support for certain Pharmaceuticals Business Unit products.



General and administrative expenses were \$11.1 million, or 27% of net revenues, for fiscal 2004, compared to \$10.4 million, or 26% of net revenue, for fiscal 2003. In fiscal 2004, legal fees of \$900,000 associated with the Beutlich and Trylon settlements offset cost reductions over the previous year.

Severance and related charges of \$350,000 in connection with employee terminations, recruiting fees and relocation expenses were incurred in fiscal 2004, compared to \$1.3 million incurred in fiscal 2003. Higher severance and related charges were incurred in the prior year due primarily to the significant changes in our management and the resulting reorganization.

Research and development expenses increased \$1.8 million, or 43%, to \$5.9 million for fiscal 2004 from \$4.1 million for fiscal 2003. The increase is due primarily to an increase in the OraTest® regulatory program expenses of \$1.9 million, or 52%, and included a non-cash charge of \$72,000 discussed below in the Biotechnology Business Unit section.

An impairment charge of \$289,000 was recorded in the Pharmaceuticals Business Unit in the fourth quarter of fiscal 2004 for IST related to the write-down of fixtures, equipment, patents and trademarks. In March 2004, our Board of Directors authorized the divestiture of the net assets of IST, our plastic molded products manufacturing subsidiary, in order to focus on our core business operations. In September 2004, we reversed the divestiture decision and withdrew IST from the market. No acceptable purchase offer was produced by the effort to market IST. Based on the results of the offer process and in accordance with the requirements of SFAS No. 144, we recognized a non-cash impairment charge to give effect to our revised estimate of the fair value of IST.

Depreciation and amortization expenses increased \$136,000, or 6%, to \$2.5 million for fiscal 2004 from \$2.3 million for fiscal 2003. The increase in depreciation and amortization relates to expenditures for property and equipment and patents and trademarks in the Nutraceuticals and Pharmaceuticals business units. These increases were mitigated by the suspension of depreciation and amortization of IST's property and equipment and patents and trademarks in April 2004 as a result of our decision to divest the net assets of IST.

On January 30, 2004, as part of our strategy to employ financial assets in core business competencies, we completed the sale and a five-year leaseback of our corporate headquarters for approximately \$1.7 million in net cash. We realized a pre-tax gain of \$1.2 million, of which we recognized approximately \$470,000 in the quarter ended January 31, 2004. The \$470,000 gain represents the excess of the net proceeds over the net present value of the future lease payments. The balance of the gain of \$765,000 was deferred and will be amortized on a straight-line basis over the five-year lease term as a reduction of rent expense in general and administrative expenses. The leaseback is accounted for as an operating lease.

### *Nutraceuticals*

Selected financial information for the Nutraceuticals Business Unit follows for the fiscal years ended July 31, 2004 and 2003 (dollars in thousands):

	Fiscal Years Ended July 31,		
	2004	2003	% Change
Net revenues:			
Ester products .....	\$32,305	\$26,077	24
Saw palmetto products .....	127	3,346	(96)
Total net revenues .....	32,432	29,423	10
Gross profit .....	20,286	17,482	16
Gross profit % .....	63%	59%	
Income from operations before income taxes .....	8,300	7,733	7

A number of factors influenced the unit revenue growth, strong profitability and other financial performance of the Nutraceuticals Business Unit in 2004, including:

- Growing consumer awareness and trial of Ester-C® in response to increased media and promotion investment and improved advertising;
- The commercial introduction of our Ester-E® tocopheryl phosphates, an enhanced form of natural vitamin E and the first line extension under our successful “Ester” umbrella of products;
- Negotiation of supply agreements for ascorbic acid that will provide a substantial portion of our annual requirements at prices equivalent to historical averages, providing cost predictability for our Ester-C® products;
- A controlled exit from the saw palmetto market, liquidating all remaining inventory at pricing that offsets our carrying value; and
- Reducing general and administrative costs from fiscal year 2003 despite significant volume growth.

Net revenues for the Nutraceuticals Business Unit for fiscal 2004 increased 10% to \$32.4 million compared to \$29.4 million for fiscal 2003. This growth was driven by an 18.0% increase in Ester-C® net revenues for fiscal 2004 over fiscal 2003 and the introduction of Ester-E® in May 2004. These increases were offset by the sharp reduction in saw palmetto oil products revenue in fiscal 2004 as we exited that business. Excluding saw palmetto, Nutraceuticals net revenues grew by 24% in fiscal 2004. Domestic net revenues for Ester-C® grew by 25% in fiscal 2004. The growth in Ester-C® net revenues was driven principally by increased radio and television advertising support for the Ester-C® products in our continuing strategy of brand development. In 2004, we completed our strategic withdrawal from the saw palmetto market by selling our remaining small inventory of saw palmetto powder in the normal course of business.

The fiscal year 2004 growth of Ester-C® continued to be driven principally by increased media spending, up 34% over the prior year. This sustained media investment, focused on increasing brand awareness for Ester-C® and introducing our Ester-E®, and this increase in media spending, led to significant distribution gains, high impact retail promotion and new manufacturer/marketer customers.

Gross profit as a percentage of net revenues increased to 63% for fiscal 2004 compared to 59% for the prior year. This increase resulted primarily from the effect of sales of the low margin saw palmetto products in the prior year as we sought to liquidate our remaining inventories and to a lesser extent sales of higher margin Ester-E® product. Higher cost of products for our Ester-C® offset our gross profit improvement. The higher cost of products for Ester-C® was caused primarily by a \$3.0 million increase in the cost of ascorbic acid, principally in the first half of fiscal 2004.

Ascorbic acid is the principal raw material in our Ester-C® products and is subject to periodic price fluctuations. While ascorbic acid prices rose dramatically during fiscal year 2003 and during the first half of fiscal year 2004, we have obtained a supply of ascorbic acid for a substantial portion of our anticipated requirements from two sources and at prices equivalent to our historical averages, providing cost predictability through the three-year terms of the agreements. Pricing under one of these agreements can fluctuate within a defined range based on foreign currency rates. On April 1, 2003, a price increase for Ester-C® products was instituted to partially offset the effects of the higher ascorbic acid prices.

Income from operations before taxes for the Nutraceuticals Business Unit for fiscal 2004, was \$8.3 million, increasing by 7% over the prior year. The primary factors contributing to this increase were the gross margin improvement described above and measures to reduce legal and employee related general and administrative expenses. Offsetting these improvements, spending for brand and media advertising support for Ester-C® increased 34% over the prior year.

During fiscal 2004, we made progress towards completion of our \$524,000 second-phase Ester-C® production expansion project to double our capacity to support approximately \$60 million in annual revenue. We also completed the \$100,000 installation of our Ester-E® production line and constructed a pilot plant

facility for new product development and current production optimization. The capital expenditures completed in fiscal 2003 resulted in a 30% increase in Ester-C® production capacity.

### Pharmaceuticals

Selected financial information for the Pharmaceuticals Business Unit follows for the fiscal years ended July 31, 2004 and 2003 (dollars in thousands):

	Fiscal Years Ended July 31,		
	2004	2003	% Change
Net revenues:			
Core Pharmaceuticals products .....	\$4,248	\$4,866	(13)
IST* .....	<u>4,723</u>	<u>4,901</u>	(4)
Total net revenues .....	8,971	9,767	(8)
Gross profit:			
Core Pharmaceuticals products gross profit .....	2,898	3,640	(20)
Core Pharmaceuticals gross margin % .....	68%	75%	
IST gross profit* .....	2,088	1,427	46
IST gross margin % .....	44%	29%	
Total gross profit .....	4,986	5,067	(2)
Total gross margin % .....	56%	52%	
Operating income (loss) before income taxes and accounting change:			
Core Pharmaceuticals products .....	(566)	522	(208)
IST* .....	<u>(199)</u>	<u>(116)</u>	(72)
Total .....	(765)	406	(288)

\* Net of intercompany eliminations

The Pharmaceuticals Business Unit has more complex operations than our Nutraceuticals Business Unit since it competes in multiple markets (consumer packaged goods, direct to dental professionals, sales to dental distributors via independent reps and swab applications) with four distribution methods (wholesalers, master distributor arrangement, independent sales representatives and direct sales team). The key factors influencing the Pharmaceuticals Business Unit's financial performance and operations during fiscal 2004 include:

- Strengthening the position of Peridex® in the direct to dental market through the introduction of new dispensing offerings;
- A disciplined product rollout of ViziLite® that resulted in improving sales trends;
- Cost of goods increases for production due to supplier changes and an increase in regulatory compliance; and
- Loss of a major IST customer.

Net revenues for the core Pharmaceuticals Business Unit for fiscal 2004 decreased 13% to \$4.2 million compared to \$4.9 million for fiscal 2003. Decreased revenues for our Peridex® product, driven largely by softer United States wholesaler demand, were primarily responsible for this decline. In 2004, Peridex® efforts were focused around strengthening our position in the direct to dental market, exclusively distributed by Omnii, through the introduction of a 64 oz. dispensing unit and a 4 oz. convenience bottle. Product development activities were initiated to counter inroads made by generic equivalents and resulted in a increase over the prior year in our "direct-to-dentist" unit sales.

During 2004, we continued to fine-tune our product-to-market strategy for ViziLite® based on our experience relating to the requirements for achieving awareness, education, trial and repeat purchases of this unique product within the dental profession. A network of independent representatives was contracted to serve as an overlay to the national network of distributors carrying ViziLite®, as well as to bring additional focus to the device during distributor representative sales calls. Additionally, the American Dental Association in May established a new reimbursement code intended to cover the ViziLite® exam. The new code became available for use beginning in January 2005. Reimbursement codes can be used to report dental procedures provided under public and private dental insurance benefits plans. Obtaining insurance reimbursement from specific carriers is a separate process. We are now engaged in this process for our ViziLite® product.

Net revenues for the Pharmaceuticals Business Unit include the net revenues of IST. Our contract with IST's major customer expired on March 31, 2004, and our net revenues from IST declined significantly during the balance of fiscal 2004. IST is actively pursuing new customer arrangements to mitigate the loss of net revenues. There can be no assurances that it will be successful in this regard. An impairment charge of \$289,000 was recorded in the Pharmaceuticals Business Unit related to IST in the fourth quarter of fiscal 2004.

Gross profit as a percentage of net revenues for the core Pharmaceuticals Business Unit decreased to 68% during fiscal 2004 from 75% for fiscal 2003, primarily due to the decrease in level of higher margin sales to United States wholesalers. The gross profit as a percentage of net revenue for IST increased to 44% during fiscal 2004 from 29% as a result of a March 2003 selling price increase for products made for our major customer and to a lesser extent from improvement in manufacturing efficiencies due to the full utilization of new machinery installed in fiscal year 2003.

Operating loss before incomes taxes for the Pharmaceuticals Business unit without IST was \$566,000 for fiscal 2004 compared to operating income of \$522,000 for the prior fiscal year. The operating loss in fiscal 2005 resulted primarily from (i) the decline in gross profit noted above. (ii) increased selling and marketing expenses to support the revised product-to-market strategy for ViziLite®; and (iii) legal expenses related to the Trylon settlement. The operating loss for IST was \$199,000 for fiscal 2004 compared to \$116,000 for the prior year. The increased operating loss for IST was primarily caused by (i) the loss of IST's major customer in March 2004, and legal fees associated with the Buetlich settlement and an impairment charge of \$289,000 recorded in the fourth quarter of fiscal 2004. The combined legal fees for the Trylon and Buetlich settlements were approximately \$900,000.

### **Biotechnology**

Selected financial information for the Biotechnology Business Unit follows for the fiscal years ended July 31, 2004 and 2003 (dollars in thousands):

	<u>Fiscal Years Ended July 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>% Change</u>
Net revenues . . . . .	\$ 2	\$ 20	(90)
Research and development . . . . .	5,476	3,610	52
Income (loss) from continuing operations before income taxes . . .	(7,195)	3,474	(307)

A number of factors have influenced the financial results for the Biotechnology Business Unit in 2004, including:

- Increased spending for the OraTest® product regulatory program;
- Selecting new regulatory consultants and continued development of a commercialization strategy for the OraTest® product;
- Proposed modifications to the current OraTest® regulatory program submitted to the FDA aimed at reducing its overall duration and total cost;

- Renegotiation of the General Services Agreement with Quintiles Transnational Corp. (“Quintiles”), our contract research organization, to support the modifications to our regulatory program;
- Expanded use of our Medical Advisory Board, whose members are some of the world’s leading researchers in the field of head and neck cancer, to assist in development of our regulatory strategy to reduce the cost and duration of our current regulatory program and in development of our product commercialization strategy;
- Emphasizing the United States domestic market sales potential and de-emphasizing European and Asian marketing efforts; and
- Evaluation of other Tolonium Chloride pre-cancer and cancer detection applications.

Revenues from sales of the OraTest® product in the United Kingdom were nominal during fiscal 2004 and 2003, as we focused on obtaining FDA approval in the United States.

Total operating expenses for the Biotechnology Business Unit were \$7.3 million for fiscal 2004, a 35% increase over the \$5.4 million for fiscal 2003. This was driven by an increase of approximately \$1.9 million, or 52%, in the regulatory program expenses related to the OraTest® product and a non-cash charge of \$72,000. As more fully described in Note 2 to the Consolidated Financial Statements, this non-cash charge relates to the removal of contractual restrictions on common stock held by The Trylon Corporation in recognition of its achievement of a product development milestone.

Operating loss before incomes taxes for the Biotechnology Business Unit was \$7.2 million for fiscal 2004 compared to operating income of \$3.5 million the prior fiscal year. Operating income for fiscal 2003 includes the contract settlement received in June 2003 from the resolution of a dispute with our former contract research organization.

### *Inflation and Seasonality*

Inflation has had no material effect on the operations or financial condition of our businesses. Our consolidated operations are not considered seasonal in nature.

### **Liquidity and Capital Resources**

#### *Overview*

Our liquidity needs arise from working capital requirements, the funding of our OraTest® regulatory program and the launch of our new products, ViziLite®, ViziLite® Plus and Ester-E®, and debt service. We have met these cash requirements through our (i) cash and cash equivalents, short-term investments, cash from operations and working capital management, (ii) the sale of non-core assets and (iii) proceeds from the issuance of common stock under our employee stock option and stock purchase programs. We also have a \$10.0 million revolving credit facility through a Credit and Security Agreement with Wells Fargo.

Selected cash flow and working capital information is set forth in the table below (dollars in thousands):

	Fiscal Years Ended July 31,	
	2005	2004
Net cash used in operating activities . . . . .	\$(7,387)	\$(3,629)
Net cash provided by (used in) investing activities . . . . .	16,588	(8,796)
Net cash provided by (used in) financing activities . . . . .	57	(56)
	<u>July 31, 2005</u>	<u>July 31, 2004</u>
Cash, cash equivalents and short-term investments . . . . .	\$12,938	\$11,680
Working capital . . . . .	22,824	22,542
Current ratio . . . . .	3.33	3.97

At July 31, 2005, our primary sources of liquidity included cash, cash equivalents and short-term investments of \$12.9 million and our line of credit (discussed below) compared to \$11.7 million at July 31, 2004. Our working capital was \$22.8 million at July 31, 2005 compared to \$22.5 million at July 31, 2004. At July 31, 2004, working capital includes IST's assets held for sale which have \$1.2 million of property, plant and equipment and patents presented as current assets as more fully described in Note 4 of the Notes to Consolidated Financial Statements. These balances were reclassified to property, plant and equipment and patents in the first quarter of fiscal 2005 upon our decision to withdraw from our efforts to sell IST. Without the effect of IST, at July 31, 2004, our working capital was \$21.3 million. The improvement in our cash and short-term investment position and in our working capital (without the effect of IST) resulted primarily from the proceeds we received from the sale of our Zilactin product line. Proceeds from the sales of the Zilactin product line and our short-term investments and from the issuance of common stock under our employee stock programs were used to fund (i) operating losses arising from our OraTest® regulatory program and our new product launches and (ii) capital expenditures for our business units.

We believe that our current cash balances, cash generated from our operations and the availability of cash under our line of credit are sufficient to finance our level of operations, the OraTest® regulatory program, the launches of ViziLite®, ViziLite® Plus, and Ester-E®, and anticipated capital expenditures.

### *Operating Activities*

Net cash used in operating activities during fiscal 2005 increased to \$7.4 million compared to \$3.6 million during fiscal 2004. The increase in net cash used in operating activities during fiscal 2005 resulted primarily from higher expenditure levels for our OraTest® regulatory program and for marketing and selling costs for our new products. The primary components in this use of cash for fiscal 2005 were the funding of our operating loss and the increase in accounts receivable arising from our increased sales levels. These uses were offset by non-cash items related primarily to depreciation and amortization and an increase in our accounts payable and accrued liabilities.

Significant changes in operating assets and liabilities were comprised of an increase in accounts receivable of \$3.4 million due to increased sales in the fourth quarter and an increase in accounts payable and accrued expenses of \$1.9 million related to professional fees for our regulatory program, Ester-E® royalties and overall growth in our business.

### *Investing Activities*

Net cash provided by investing activities during fiscal 2005 increased to \$16.6 million compared to net cash used in investing activities of \$8.8 million during fiscal 2004. During fiscal 2005, net cash was provided from the \$11.0 million in proceeds from the sale of our Zilactin product line and \$8.0 million in proceeds from sales of our short-term investments in auction rate securities. These proceeds were offset by expenditures for capital asset purchases and expenditures for patents and trademarks. During fiscal year 2004, the principal component in the net cash used in investing activities was the \$8.0 million used to purchase our net investment in auction rate securities. During fiscal 2004, we placed \$517,000 in an interest bearing collateral account required by the letter of credit for the Zila Nutraceuticals industrial revenues bonds discussed below.

Capital expenditures for property and equipment were \$1.9 million in fiscal 2005 compared to \$1.3 million in fiscal 2004. Our capital expenditures in fiscal 2005 were directed toward investments in (i) a new Ester-C® production line in the Nutraceuticals Business Unit and (ii) re-commissioning of the ZTC™ facility in the Biotechnology Business Unit.

### *Financing Activities*

Net cash provided by financing activities during fiscal 2005 was \$57,000 compared to net cash used in financing activities of \$56,000 during fiscal 2004. Proceeds from issuance of our common stock under our employee stock plans and short-term borrowings offset payments on the outstanding principal balance of the bonds related to Zila Nutraceuticals facility and dividends paid on our outstanding preferred stock.

### *Income Taxes*

At July 31, 2005, we had net operating loss (“NOL”) carry forwards for federal tax purposes of approximately \$11.3 million that expire in years 2009 through 2024. Our ability to utilize the federal NOL carry forwards may be impaired if we continue to incur operating losses. Valuation allowances were provided for the entire amount of our net deferred tax assets.

### *Credit Facilities*

On February 6, 2004, our subsidiaries, Zila Nutraceuticals, Inc., Zila Pharmaceuticals, Inc., Zila Biotechnology, Inc., Zila Swab Technologies, Inc., and Oxycal Laboratories, Inc., entered into a Credit and Security Agreement (the “Wells Fargo Agreement”) with Wells Fargo Business Credit, Inc. (“Wells Fargo”) that provides a \$10 million revolving line of credit effective on August 17, 2004 upon the expiration of the Congress Agreement and upon the perfection of certain security interests by Wells Fargo. Borrowings will bear interest equal to the prime rate. Funds available under the Wells Fargo Agreement are based upon a percentage of the value of eligible receivables and inventory. Obligations under the Wells Fargo Agreement are collateralized by various assets, including, but not limited to trade accounts receivable, inventories, equipment and intangible assets. The parent company, Zila, Inc., guarantees the obligations under the Wells Fargo Agreement.

Under the Wells Fargo Agreement, we were required to maintain defined minimum levels of net worth at the end of each fiscal quarter and to limit capital expenditures to \$3.0 million in fiscal 2005. Our minimum net worth requirement under the Wells Fargo Agreement varies each quarter in relation to our planned operating results. At July 31, 2005, our net worth, as defined, was \$51.7 million compared to the required amount of \$39.0 million. Additionally, payment of dividends on our common stock is restricted. The net worth and capital expenditures covenants are established annually as of August 1. The Wells Fargo Agreement contains a provision whereby Wells Fargo can call for immediate repayment of all amounts due under the line upon its sole determination that a “material adverse change” has occurred. As a result of this provision, any borrowings under the Wells Fargo Agreement will be classified as short-term debt. There have been no borrowings under the Wells Fargo Agreement.

In April 1999, Zila Nutraceuticals, Inc. entered into a transaction with The Industrial Development Authority of the County of Yavapai (the “Authority”) in which the Authority issued Industrial Development Revenue Bonds (the “Bonds”). The proceeds from the Bonds were loaned to Zila Nutraceuticals, Inc. for the construction of a new manufacturing and laboratory facility. The initial offerings of Bonds consisted of \$3.9 million Series A and \$104,000 Taxable Series B Bonds and mature in 2019. The Series B Bonds were repaid. The Bonds bear a variable interest rate that was 2.5% at July 31, 2005. In connection with the issuance of the Bonds, the Authority required that Zila Nutraceuticals, Inc. maintain, for the benefit of the Bondholders, an irrevocable direct-pay letter of credit to secure payment of principal and interest. Zila, Inc. guarantees the letter of credit. Wells Fargo provides such letter of credit (“Replacement Letter of Credit”) in conjunction with the Wells Fargo Agreement. This Replacement Letter of Credit replaced an earlier letter of credit provided by Bank One, which expired in March 2004.

Under the terms of the Replacement Letter of Credit, on February 6, 2004, we placed \$517,000 in an interest bearing collateral account representing the difference between the Replacement Letter of Credit amount and the maximum commitment amount, as defined.

In December 2002, we entered into an agreement with PharmaBio Development, Inc. (“PharmaBio”), the strategic investment group of Quintiles Transnational Corp., our contract research organization. Under this agreement, PharmaBio invested \$500,000 in us. In return for the investment, we agreed to pay PharmaBio an amount equal to 5.0% of all net sales of the OraTest® product in the European Union and the United States. The aggregated amount of the royalty cannot exceed \$1.25 million and the royalty is payable quarterly. The investment was recorded as long-term debt and will be amortized using the effective interest method.

### *Supply Arrangements*

In the ordinary course of its business, our wholly-owned subsidiary, Zila Nutraceuticals, Inc., purchases ascorbic acid from several direct and broker-arranged suppliers. Zila Nutraceuticals, Inc. entered into three-year supply agreements with two major producers for the purchase of \$26.7 million of ascorbic acid of which \$21.0 million remains to be purchased in future periods. Ascorbic acid is the primary ingredient in our Ester-C® products. Purchases under one of these agreements commenced in July 2004, with the other agreement starting in January 2005. The agreements provide a substantial portion of our anticipated annual requirements for ascorbic acid and will provide important cost predictability during the terms of the agreements. If ascorbic acid prices decline sharply, we would be at risk of being committed to purchase ascorbic acid at higher than market prices. Additionally, if our sales were to significantly decline, we would be obligated to purchase ascorbic acid in excess of our needs.

### *Preferred Stock*

On February 5, 2001, we issued 100,000 shares of Series B Convertible Preferred Stock ("Series B Preferred") as part of the IST acquisition. The holders of the Series B Preferred are entitled to receive cumulative quarterly dividends at a rate of \$0.0975 per share per fiscal quarter, payable in arrears. We paid dividends of \$68,250, \$19,500 and \$49,000 during fiscal 2005, 2004, and 2003, respectively. At July 31, 2005, accumulated accrued dividends are \$9,750. The Series B Preferred can be redeemed at our option if our common stock maintains a closing price on each trading day equal to or greater than \$9.00 per share for any ten trading day period. The redemption price shall be the average bid closing price on our common stock for the five trading days immediately preceding the date we give notice. The Series B Preferred shall be convertible at the option of the holder at any time on or before December 31, 2010 into our common stock at the ratio of one-to-one. On December 31, 2010, all of the remaining Series B Preferred will be converted into our common stock at a ratio of one-to-one.

### *Stock Repurchase Program*

On November 10, 1999, we announced that our Board of Directors authorized the repurchase of up to one million shares of Zila common stock from time to time on the open market depending on market conditions and other factors. As of July 31, 2005, 225,100 shares had been repurchased for \$571,400. We made no purchases pursuant to this program since fiscal 2003, and we have currently suspended purchases under this program.

### *EBITDA*

The following discussion includes a presentation of EBITDA, which is utilized by management as one measure of the performance of our business units. We consider EBITDA to be a meaningful measure of our ongoing operations that assists us in assessing our ability to fund our regulatory program and debt service and to finance the growth of our core businesses.

Although we use EBITDA as a financial measure to assess the performance of our business, we do not use EBITDA alone because it does not consider certain material costs, expenses and other items necessary to operate our business. These items include debt service costs and non-cash depreciation and amortization expense associated with long-lived assets. Because EBITDA does not consider these items, a user of our financial information should also consider net income as an important measure of our financial performance in that it provides a more complete measure of our performance.



**Reconciliation of GAAP Measures to Non-GAAP Measures**  
(In thousands)

	Fiscal Years Ended July 31,		
	2005	2004	2003
EBITDA .....	\$ 3,939	\$(1,431)	\$10,264
Interest income .....	188	109	15
Interest expense .....	(196)	(342)	(389)
Depreciation and amortization .....	(2,746)	(2,671)	(2,417)
Income tax expense .....	(86)	(2)	(188)
Net income (loss) .....	<u>\$ 1,099</u>	<u>\$(4,337)</u>	<u>\$ 7,285</u> (a)

(a) Fiscal 2003 net income includes a \$14.8 million net contract settlement gain from our former contract research organization and goodwill impairment charge of \$4.1 million (see Notes 6 and 9 of Notes to Consolidated Financial Statements).

**Contractual Obligations**

The table below summarizes our future cash contractual obligations at July 31, 2005, and the effect that such obligations are expected to have on our liquidity and cash flows for fiscal years ending July 31 (in thousands).

	2006	2007 & 2008	2009 & 2010	Thereafter	Total
Long-term debt .....	\$ 274	\$ 491	\$ 991	\$1,740	\$ 3,496
Operating leases .....	476	887	488	69	1,920
Capital lease obligations .....	54	98	13	—	165
Purchase obligations .....	<u>9,208</u>	<u>11,801</u>	<u>—</u>	<u>—</u>	<u>21,009</u>
Total .....	<u>\$10,012</u>	<u>\$13,277</u>	<u>\$1,492</u>	<u>\$1,809</u>	<u>\$26,590</u>

Purchase obligations include contractual arrangements for the purchase of raw materials that are legally binding and enforceable. These contractual arrangements specify all significant terms, including: fixed or minimum quantities to be purchased, pricing provisions and the approximate timing of the transaction. The timing of payments for our purchase obligations is estimated based upon current information. The actual timing and amount of payment may differ from this estimate.

Purchase orders for raw materials and other goods and services are not included in the above table. Our purchase orders may represent authorizations to purchase rather than definitive binding contractual obligations. Contractual arrangements for goods and services that contain clauses allowing for cancellation without significant penalty are not included in the above table.

**Critical Accounting Policies and Estimates**

There are several accounting policies that we believe are significant to the presentation of our consolidated financial statements and require management's most difficult, complex or subjective judgments about matters that are inherently uncertain. Note 1 to our consolidated financial statements "Nature of Business Activities and Summary of Significant Accounting Policies" summarizes each of our significant accounting policies. We believe our most critical accounting policies are as follows:

*Revenue Recognition* — Revenue from sales of products is recognized when earned; that is, when the risks and rewards of ownership have transferred to the customer, which is considered to have occurred when

delivery to the designated location or carrier has occurred. Cash discounts, sales incentives, and returns are estimated and recognized as a reduction of revenue at the time of sale based upon historical activity and current customer commitments. We evaluate these estimates on a quarterly basis and revise them as necessary.

We provide for allowances for doubtful accounts and sales returns based on historical experience and a review of our receivables. Receivables are presented net of allowances for doubtful accounts and for sales returns of \$150,000 at July 31, 2005 and \$272,000 at July 31, 2004. We evaluate these estimates on a quarterly basis and revise them as necessary.

On occasion, we enter into arrangements to license our technology on specifically approved products. For those arrangements where we have continuing involvement with the licensee, nonrefundable, upfront license fees are recognized systematically as they are earned over the life of the agreement. Fees associated with substantive, at risk, performance milestones are recognized as revenue upon their completion, as defined in the respective agreements. For perpetual licenses or manufacturing rights agreements, where: (i) we have no further continuing involvement with the licensee; (ii) the fees are nonrefundable; and (iii) the fees are not a prepayment of future royalties, we recognize the fees as revenue at the time the arrangement becomes effective. The assessment of existence or extent of continuing involvement requires significant judgment and analysis of the contractual requirements and other factors relating to the business relationship between the parties.

*Use of Estimates* — The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America necessarily requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, as well as disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. The accounting estimates used in the preparation of our consolidated financial statements will change as new events occur, as more experience is acquired, as additional information is obtained and as our operating environment changes. Actual results could differ from those estimates.

Significant estimates include: (i) useful lives of intangibles; (ii) impairment analyses; (iii) depreciable lives of assets; (iv) income tax valuation allowances; (v) contingency and litigation reserves; (vi) inventory valuation; and (vii) allowances for accounts receivable, cash discounts, sales incentives and sales returns.

We make changes in estimates as appropriate, and as we become aware of circumstances surrounding those estimates. Such changes and refinements in estimation methodologies are reflected in reported results of operations in the period in which the changes are made and, if material, their effects are disclosed in the Notes to Consolidated Financial Statements.

Our impairment analyses include significant estimates with respect to cash flows and fair values. The factors that affect these estimates include the following:

The cash flows used to measure long-lived assets related to the OraTest® product are dependent upon obtaining FDA approval and generating sufficient revenues from sales of the OraTest® product. The rigorous clinical testing and an extensive regulatory approval process mandated by the FDA and equivalent foreign authorities before any new drug can be marketed by us can take a number of years and require the expenditure of substantial resources. Obtaining such approvals and completing such testing is a costly and time-consuming process, and approval may not be ultimately obtained. The length of the FDA review period varies considerably, as does the amount of clinical data required to demonstrate the safety and efficacy of a specific product. Net long-lived assets related to the OraTest® product as of July 31, 2005 of \$5.8 million have been capitalized.

The cash flows used to measure long-lived assets related to the ViziLite® products are dependent upon our ability to properly market the products to a sufficient number of dentists so they become integrated within their practice. ViziLite® is a chemiluminescent light technology used in combination with traditional oral screening to increase identification, evaluation and monitoring of oral mucosal

abnormalities. Achieving our sales goals requires significant training and education about the products' attributes to the dental professionals. As a result of organizational and sales strategy changes in 2003 and 2004, we have revised our business model with current sales and costs assumptions. We have added significant marketing, sales and educational costs targeted towards achieving market acceptance within a reasonable timeframe. Net long-lived assets related to the ViziLite® products as of July 31, 2005 of \$1.8 million have been capitalized.

*Goodwill, Intangibles and Other Long-Lived Assets* — We have made acquisitions of products and businesses that include goodwill, license agreements, patents and trademarks, product rights and other intangible and long-lived assets. We assess the impairment of goodwill, intangibles and other long-lived assets whenever events or changes in circumstances indicate that the carrying value of any of these assets may not be recoverable. Such events or circumstances might include a significant decline in market share and/or significant negative industry or economic trends, a significant decline in profits and/or significant underperformance relative to expected historical or projected operating results, significant changes in the manner of our use of the acquired assets or the strategy for our overall business, rapid changes in technology, significant litigation or other items. In evaluating the recoverability of goodwill, intangibles and other long-lived assets, our policy is to compare the carrying amounts of such assets with the estimated undiscounted future operating cash flows. If we have changes in events or circumstances, including reductions in anticipated cash flows generated by our operations or determinations to divest of certain assets, certain assets could be impaired which would result in a charge to earnings.

In accordance with SFAS No. 142 — “Goodwill and Other Intangibles,” our policy is to review the carrying amounts of goodwill and certain intangible assets with indefinite lives at least annually as of May 1 or, as described above, whenever events or changes in circumstances indicate that the carrying amount of the asset may be impaired.

The following is a summary of the significant components of our goodwill and intangible assets and our impairment methodology for each.

*Zila Pharmaceuticals Goodwill* — Goodwill is related to the Peridex® product which was acquired from Procter & Gamble in November 1997 and to the IST acquisition in February 2001. As part of the implementation for SFAS No. 142, “Goodwill and Other Intangible Assets” on August 1, 2002, the Company retained an independent financial advisor who compared the fair values and corresponding carrying values of the Peridex® and IST assets as of the adoption date for SFAS No. 142. Based upon the financial advisor’s findings, we determined that approximately \$3.0 million of the Peridex® goodwill and the entire \$1.1 million of IST goodwill was impaired thus reducing goodwill to approximately \$4.1 million. This transitional impairment charge of \$4.1 million was recorded as a change in accounting principle and retroactively restated to August 1, 2002, the beginning of our fiscal year. We review the carrying value of Zila Pharmaceuticals goodwill at least annually as of May 1 or, as described above, whenever events or changes in circumstances indicate that the carrying amount of the asset may be impaired.

*Zila Nutraceuticals Goodwill* — Goodwill and trademarks totaling approximately \$10.6 million (net of accumulated amortization of \$4.3 million) are related to the Ester-C® group of products. These assets were acquired by merger in 1997 and are combined for purposes of testing for impairment. We review the carrying value of Zila Nutraceuticals goodwill at least annually as of May 1 or, as described above, whenever events or changes in circumstances indicate that the carrying amount of the asset may be impaired.

*OraTest®* — The purchase of CTM eliminated our obligation to pay royalties to CTM on future sales of the OraTest® product. The recoverability of the \$3.0 million net purchased technology rights is dependent upon obtaining FDA approval and generating sufficient revenues from future sales of the OraTest® products. For purposes of testing recoverability, the following are grouped with purchased technology rights: (i) fixed assets of approximately \$1.2 million (primarily related to our manufacturing facility); (ii) patents and patents pending of \$1.6 million; and (iii) \$482,000 of OraTest® clinical rinse and swab inventory, ZTC™ drug substance, the active ingredient in the OraTest® product, and its related

components. We have prepared a probability-weighted analysis of potential future cash flows under various possible outcomes. Significant assumptions in the analysis include the expected date and overall likelihood of FDA approval, cost of the remaining regulatory program, cost of the marketing roll out, future net cash flows associated with sales of the products and the probabilities assigned to each possible outcome. The assumptions included in the analysis are updated whenever events or changes in circumstances indicate that the carrying amount may be impaired.

### **Recent Accounting Pronouncements**

In June 2005, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 154, "Accounting Changes and Error Corrections" ("SFAS No. 154"), a replacement of APB Opinion No. 20, "Accounting Changes" and FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements." SFAS No. 154 applies to all voluntary changes in accounting principle and changes the requirements for accounting for and reporting a change in accounting principle. SFAS No. 154 requires the retrospective application to prior periods' financial statements of the direct effect of a voluntary change in accounting principle unless it is impracticable. APB No. 20 required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. The FASB stated that SFAS No. 154 improves financial reporting because its requirements enhance the consistency of financial information between periods. Unless early adoption is elected, SFAS No. 154 is effective for fiscal years beginning after December 15, 2005. Early adoption is permitted for fiscal years beginning after June 1, 2005. SFAS No. 154 does not change the transition provisions of any existing accounting pronouncements, including those that are in a transition phase as of the effective date of this statement. We will adopt SFAS No. 154 on August 1, 2005, the beginning of our next fiscal year.

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R is a revision of FASB Statement No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123") and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and its related implementation guidance. As permitted under SFAS No. 123, we currently account for stock options under APB Opinion No. 25 whereby (i) stock options are granted at market price and (ii) no compensation expense is recognized since the exercise price equals the stock price on the grant date, and we disclose the pro forma effect on net earnings assuming that compensation cost had been recognized under the requirements of SFAS No. 123. SFAS No. 123R requires companies to measure and recognize compensation expense for all stock-based payments at fair value. Stock-based payments include stock option grants. We grant options to purchase common stock to some of our employees and directors at prices equal to the market value of the stock on the dates the options were granted. SFAS No. 123R is effective for us beginning August 1, 2005, the beginning of our next fiscal year. SFAS No. 123R permits public companies to adopt its requirements using one of two methods: (i) a "modified prospective" method in which the requirements of SFAS No. 123R apply for all share-based payments granted or modified after the effective date, and to any unvested awards as service is rendered on or after the effective date or (ii) a "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits companies to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either for all periods presented or prior interim periods of the year of adoption. We will adopt SFAS No. 123R using the modified prospective method and expect the adoption of this standard will have an unfavorable impact on our consolidated results of operations and net income per common share. Note 1 — *Stock Options* illustrates the pro forma effects on net income and earnings per share as if we had adopted SFAS No. 123 using the Black-Scholes option-pricing model. However, the impact on future periods will depend on, among other things, the number of share-based awards granted and variables such as the volatility of our stock and when employees exercise stock options.

On March 3, 2005 our Board of Directors approved the immediate vesting of all outstanding and unvested stock options previously granted under our Stock Award Plan to officers and employees, for which the option

exercise price was above the closing price for our common stock on April 29, 2005. On such date, the closing price was \$3.09. Options held by non-employee directors were excluded from this acceleration. The immediate vesting of these options will avoid the compensation expense in future periods on these options which were granted prior to the implementation of SFAS No. 123R.

In December 2004, the FASB issued FASB Staff Position No. FAS 109-1, "Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004 (AJCA)." The AJCA was signed into law in October 2004 and includes a tax deduction of up to 9 percent (when fully phased in) of the lesser of (i) "qualified production activities income" as defined in the Act, or (ii) taxable income (after the deduction for domestic manufacturing) from this legislation should be accounted for as a "special deduction" instead of a tax rate reduction. We will be able to start claiming this deduction in our fiscal 2006. We expect that the adoption of SFAS No. 109-1 will not have a material impact on our financial position or results of operations.

In November 2004, the FASB issued Statement of Financial Accounting Standards No. 151 "Inventory Costs — an amendment of ARB No. 43, Chapter 4" ("SFAS No. 151") effective for fiscal years beginning after June 15, 2005. SFAS No. 151 will become effective for us on August 1, 2005, the beginning of our next fiscal year. This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). This Statement requires that those items be recognized as current-period charges. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. We believe that the adoption of SFAS No. 151 will not have a material effect on our financial position or results of operations.

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

We are exposed to market risks primarily from interest rates and from changes in foreign currency exchange rates, as well as changes in our credit standing. In addition, a market risk exists associated with the cost of ascorbic acid, a raw material used in our Nutraceuticals Business Unit. In fiscal 2004 we executed extended-term supply contracts to mitigate the risk of increased cost of ascorbic acid.

At July 31, 2005, we had a revolving line of credit with Wells Fargo Business Credit with a variable interest rate equal to the prime rate announced by Wells Fargo Bank, NA (6.25% at July 31, 2005). At July 31, 2005, no borrowings were outstanding under this line of credit. The impact of a 10% proportional increase in average interest rates would not be expected to have a material effect since average outstanding balances under our revolving credit facility are not expected to be significant. We also have long-term debt associated with the Industrial Development Revenue Bonds ("Bonds") that carries a variable interest rate. The rate is set weekly by JP Morgan Chase Bank and fluctuates based on market conditions and was 2.5% per annum at July 31, 2005. A 10% proportional increase in the average interest rate on the bonds would increase annual interest expense by less than \$10,000.

We have certain exposures to foreign currency risk through our subsidiaries that conduct business in Canada and Europe and through a subsidiary that uses the British pound as its functional currency. Additionally, under one of our ascorbic acid supply agreements, we are subject to defined pricing adjustments based on fluctuations in foreign currency. We believe that such exposure does not present a significant risk due to the limited number of transactions and/or accounts denominated in foreign currency.

With respect to our ascorbic acid supply arrangements, if ascorbic acid prices decline sharply, we would be at risk of being committed to purchase ascorbic acid at higher than market prices. Additionally, if our sales were to significantly decline, we would be obligated to purchase ascorbic acid in excess of our needs.

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

Consolidated financial statements, together with the related notes and the reports of BDO Seidman, LLP and Deloitte & Touche LLP, independent registered public accounting firms, are set forth hereafter. Other required financial information and schedules are set forth herein, as more fully described in Item 15 hereof.

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

Pursuant to a Form 8-K filed on November 18, 2004, we disclosed that on November 12, 2004, the Audit Committee of our Board of Directors dismissed Deloitte & Touche LLP (“Deloitte”) as our independent registered public accounting firm. Thereafter, on November 12, 2004, we retained the services of BDO Seidman, LLP (“BDO Seidman”) as our new independent registered public accounting firm.

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

### **Evaluation of Disclosure Controls and Procedures.**

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) that are designed: (i) to ensure that information required to be disclosed in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and (ii) to ensure that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report, and, based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) are effective.

### **Changes in Internal Control over Financial Reporting.**

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Management’s Annual Report on Internal Control Over Financial Reporting.**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined by Exchange Act Rule 13a-15(f) and 15(d)-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of our financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with the authorizations of our management and board of directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

An internal control system, no matter how well conceived and operated, can provide only reasonable — not absolute — assurance that the objectives of a control system are met. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all controls issues, if any, within a company have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our principal executive officer and principal financial officer conducted an assessment of the effectiveness of our internal control over financial reporting as of July 31, 2005, based on the framework and criteria set forth in Internal Control — Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). Based on our assessment, management concluded that we maintained effective internal control over financial reporting as of July 31, 2005 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external reporting purposes in accordance with generally accepted accounting principles. Our management reviewed the results of our assessment with our Audit Committee and our Board of Directors.

BDO Seidman, LLP, the independent registered public accounting firm that audited our consolidated financial statements for the fiscal year ended July 31, 2005 included in this Annual Report on Form 10-K, has issued a report on management’s assessment of the effectiveness of our internal control over financial reporting as of July 31, 2005. Their report is included herein under the heading “Report of Independent Registered Public Accounting Firm.”

## Report of Independent Registered Public Accounting Firm On Internal Control Over Financial Reporting.

Board of Directors and Shareholders  
Zila, Inc.  
Phoenix, Arizona

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting that Zila, Inc. maintained effective internal control over financial reporting as of July 31, 2005, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of July 31, 2005, is fairly stated, in all material respects, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of July 31, 2005, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Zila, Inc. and subsidiaries as of July 31, 2005 and the related consolidated statements of operations, comprehensive income, shareholders' equity, and cash flows for the year then ended, and our report dated October 5, 2005 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Phoenix, Arizona  
October 5, 2005



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

Not applicable.

**PART III**

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

The information required by this item relating to our directors and nominees, and regarding compliance with Section 16(a) of the Securities Act of 1934, is included under the captions "Proposal One: Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for the annual meeting of stockholders of Zila to be held on December 15, 2005 (the "Proxy Statement") and is incorporated herein by reference.

Pursuant to General Instruction G(3) of Form 10-K, the information required by this item relating to our executive officers is included under the caption "Executive Officers" in the Proxy Statement.

We have adopted a code of ethics that applies to our principal executive officer and all members of our finance department, including the principal financial officer and principal accounting officer. This code of ethics is posted on the Investor Relations portion of our website at [www.zila.com](http://www.zila.com) and is titled "Zila, Inc. Code of Business Conduct." We intend to satisfy any disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics relating to an executive officer by posting such information on our website.

**Item 11. *Executive Compensation***

The information required by this item is included under the captions "Proposal One: Election of Directors — Board Compensation" and "Executive Compensation and Other Information" in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item relating to security ownership of certain beneficial owners and management is included under the caption "ZILA Share Ownership," and the information required by this item relating to securities authorized for issuance under equity compensation plans is included under the caption "Equity Compensation Plan Information," in each case in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item is included under the caption "Certain Relationships and Related Transactions" in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item is included under the captions "Proposal Two: Ratification of Independent Registered Public Accounting Firm" in our Proxy Statement and is incorporated herein by reference.

## PART IV

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

- (a) (1) Financial Statements. Reference is made to the financial statements list in Section 1 of the Index to Consolidated Financial Statements and Schedules in this Report.
- (a) (2) Financial Statement Schedule. Reference is made to the financial statement schedule listed in Section 2 of the Index to Consolidated Financial Statements and Schedules in this Report. All other schedules have been omitted as not required, not applicable or because the information required to be presented is included in the financial statements and related notes.
- (a) (3) The exhibits listed in the accompanying Index to Exhibits filed as part of this Report are incorporated herein by reference.

### INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>	<u>Method of Filing</u>
3-A	Certificate of Incorporation, as amended	A
3-B	Certificate of Amendment to Certificate of Incorporation	*
3-C	Amended and Restated Bylaws (as amended through September 26, 2002)	B
4-A	Specimen Stock Certificate	A
10-A	Asset Purchase Agreement dated October 28, 1999 between Zila, Inc., and Cygnus Imaging, Inc. and Procure Laboratories, Inc.	A
10-B	Secured Note dated October 28, 1999 between Zila, Inc. and Procure Laboratories, Inc.	A
10-C	Asset Purchase agreement dated as of November 30, 1999 by and among Zila, Inc., Integrated Dental Technologies, Inc., InfoCure Systems, Inc., and InfoCure Corporation	C
10-D	Engagement Letter dated March 15, 2001 between Zila, Inc. and Douglas, Curtis and Allyn, LLC	D
10-E	Employee Stock Purchase Plan(1)	E
10-F	Asset Purchase Agreement, dated as of November 1, 2001, by and between Ryker Dental of Kentucky, Inc. and HSI Ryker, Inc.	F
10-G	Amended and Restated Asset Purchase Agreement dated as of December 4, 2001 by and among Zila, Inc., Ryker Dental of Kentucky, Inc. and PracticeWares, Inc.	F
10-H	First Amendment to Engagement Letter dated as of June 6, 2002 between Zila, Inc. and Douglas, Curtis & Allyn, LLC	G
10-I	Fourth Extension and Modification Agreement dated as of June 6, 2002 between Ryker Dental of Kentucky, Inc., PracticeWares, Inc. and Practice Works, Inc. and Gregory A. Jones	G
10-J	First Amendment to Amended and Restated Asset Purchase Agreement dated as of June 18, 2002 between Ryker Dental of Kentucky, Inc., PracticeWares, Inc. and Zila, Inc	G
10-K	Stockholders Agreement dated as of June 18, 2002, among PracticeWorks, Inc., Gregory A Jones, Ryker Dental of Kentucky, Inc. and PracticeWares, Inc	G
10-L	Investment Agreement between Zila, Inc. and PharmaBio Development, Inc. dated December 18, 2002	H
10-M	Credit and Security Agreement between Zila Nutraceuticals, Inc., Zila Biotechnology, Inc., Zila Pharmaceuticals, Inc., Zila Swab Technologies, Inc., Oxycal Laboratories, Incorporated, and Wells Fargo Business Credit, Inc., date as of February 6, 2004	I

<u>Exhibit Number</u>	<u>Description</u>	<u>Method of Filing</u>
10-N	Reimbursement Agreement between Oxycal Laboratories, Incorporated, an Arizona Corporation, and Wells Fargo Business Credit, Inc. relating to \$3,900,000 — The Industrial Development Authority Revenue Bonds (Oxycal Laboratories, Incorporated Project) Series 1999A, dated as of February 6, 2004	I
10-O	Employment Agreement between Zila, Inc. and Douglas D. Burkett, Ph.D., dated as of October 21, 2003(1)	I
10-P	Purchase Agreement between Zila, Inc. and Gary and Janet Hedge, dated as of November 7, 2003	I
10-Q	Lease between Zila, Inc. and Phoenix 7 LLC, dated January 30, 2004	I
10-R	Offer letter between Zila, Inc. and Andrew A. Stevens dated January 15, 2004(1)	J
10-S	First Amendment dated August 17, 2004 to the Credit and Security Agreement dated February 6, 2004 by and between Wells Fargo Business Credit, Inc. and Zila Nutraceuticals, Inc., Zila Biotechnology, Inc., Zila Pharmaceuticals, Inc., Zila Swab Technologies, Inc., and Oxycal Laboratories, Incorporated	J
10-T	1997 Stock Award Plan, as amended effective December 16, 2004(1)	K
10-U	Second Amendment to the Credit and Security Agreement with Wells Fargo Business Credit, Inc. and Zila Nutraceuticals, Inc., Zila Biotechnology, Inc., Zila Pharmaceuticals, Inc., Zila Swab Technologies, Inc., and Oxycal Laboratories, Incorporated	L
10-V	Offer letter between Zila, Inc. and Gary V. Klinefelter dated November 16, 2004(1)	M
10-W	Retention Agreement with Andrew A. Stevens effective March 7, 2005(1)	M
10-X	Retention Agreement with Betty J. Pecha effective March 7, 2005(1)	M
10-Y	Retention Agreement with Diane E. Klein effective March 7, 2005(1)	M
10-Z	Agreement of Purchase and Sale of Assets dated June 27, 2005 with Blair Laboratories, Inc.	*
10-Aa	2006 Executive Incentive Bonus Plan(1)	*
10-Ab	2006 Employees Incentive Bonus Plan(1)	*
10-Ac	Form of Option Agreement	*
21	Subsidiaries of Registrant	*
23.1	Consent of BDO Seidman, LLP, Independent Registered Public Accounting Firm	*
23.2	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm	*
24.1	Power of Attorney (included on page 53 of this Annual Report on Form 10-K)	*
31.1	Sarbanes-Oxley Section 302 Certification of the Chief Executive Officer	*
31.2	Sarbanes-Oxley Section 302 Certification of the Chief Financial Officer	*
32.1	Sarbanes-Oxley Section 906 Certification of the Chief Executive Officer	**
32.2	Sarbanes-Oxley Section 906 Certification of the Chief Financial Officer	**

(1) Management contract or compensatory plan or arrangement

\* Filed herewith

\*\* Furnished herewith

A Incorporated by reference to the Company's Annual Report on Form 10-K for fiscal year ended July 31, 1999

B Incorporated by reference to the Company's Annual Report on Form 10-K for fiscal year ended July 31, 2002

C Incorporated by reference to the Company's Current Report on Form 8-K dated January 3, 2000

D Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended April 30, 2001

- E Incorporated by reference to the Company's Proxy Statement on Schedule 14A filed November 7, 2000
- F Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended October 31, 2001
- G Incorporated by reference to the Company's Current Report on Form 8-K dated July 3, 2002
- H Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended January 31, 2003
- I Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended January 31, 2004
- J Incorporated by reference to the Company's Annual Report on Form 10-K for fiscal year ended July 31, 2004
- K Incorporated by reference to the Company's Proxy Statement on Schedule 14A filed November 8, 2004
- L Incorporated by reference to the Company's Current Report on Form 8-K dated January 25, 2005
- M Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended January 31, 2005

## 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 on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, this 12th day of October, 2005.

ZILA, INC., a Delaware corporation

By           /s/  ANDREW A. STEVENS          

Andrew A. Stevens  
*Vice President and Chief Financial Officer*  
*(Principal Financial Officer)*

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Andrew A Stevens his or her attorney-in-fact, with the full power of substitution, for such person, in any and all capacities, to sign the Zila, Inc. Annual Report on Form 10-K and all amendments thereto, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might do or could do in person hereby ratifying and confirming all that each of said attorneys-in-fact and agents, or his substitute, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report on Form 10-K has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ DOUGLAS D. BURKETT, PH.D.</u> Douglas D. Burkett, Ph.D.	Chairman of the Board, President, and Chief Executive Officer	October 12, 2005
<u>/s/ MORRIS C. AARON</u> Morris C. Aaron	Director	October 12, 2005
<u>/s/ LESLIE GREEN</u> Leslie Green	Director	October 12, 2005
<u>/s/ CHRISTOPHER D. JOHNSON</u> Christopher D. Johnson	Director	October 12, 2005
<u>/s/ MICHAEL S. LESSER</u> Michael S. Lesser	Director	October 12, 2005

Signature

Title

Date

/s/ JOHN EDWARD PORTER  
John Edward Porter

Director

October 12, 2005

/s/ S. TIMOTHY ROSE  
S. Timothy Rose

Director

October 12, 2005

**ZILA, INC. AND SUBSIDIARIES**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS AND**  
**FINANCIAL STATEMENT SCHEDULE**

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## Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders  
Zila, Inc.  
Phoenix, Arizona

We have audited the accompanying consolidated balance sheet of Zila, Inc. and subsidiaries as of July 31, 2005 and the related consolidated statements of operations, comprehensive income, shareholders' equity, and cash flows for the year then ended. We have also audited the schedule listed in the accompanying index. 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 audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Zila, Inc. and subsidiaries at July 31, 2005, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Also, in our opinion, the schedule presents fairly, in all material respects, the information set forth therein.

As more fully described in Note 1 to the consolidated financial statements, during the quarter ended April 30, 2005, Zila, Inc. changed the date of their annual goodwill impairment test under Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets*, to the first day of their fourth fiscal quarter (May 1, 2005).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Zila Inc.'s internal control over financial reporting as of July 31, 2005, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated October 5, 2005 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Phoenix, Arizona  
October 5, 2005



## Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders  
Zila, Inc.  
Phoenix, Arizona

We have audited the accompanying consolidated balance sheet of Zila, Inc. and subsidiaries (the "Company") as of July 31, 2004, and the related consolidated statements of operations, comprehensive income (loss), shareholders' equity, and cash flows for each of the two years in the period ended July 31, 2004. Our audits also included the financial statement schedule listed in the Index at Item 15(a)(3). These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Zila, Inc. and subsidiaries as of July 31, 2004, and the results of their operations and their cash flows for each of the two years in the period ended July 31, 2004, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, in 2003 the Company changed its method of accounting for goodwill and other intangible assets to conform to Statement of Financial Accounting Standards No. 142.

As discussed in Note 3 to the consolidated financial statements, on June 27, 2005 the Company sold substantially all of the assets of its Zilactin brand over-the-counter lip and oral care products. Zilactin's results of operations have been classified as discontinued operations in all periods presented.

/s/ DELOITTE & TOUCHE LLP

Phoenix, Arizona  
October 13, 2004 (October 7, 2005 as to the effects of the discontinued operation described in Note 3)

**ZILA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**July 31, 2005 and 2004**

	<b>2005</b>	<b>2004</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents .....	\$ 12,937,517	\$ 3,679,915
Short-term investments .....	—	8,000,000
Restricted cash collateral .....	527,783	517,353
Trade receivables — net of allowances of \$150,000 and \$272,000 .....	11,422,743	8,027,341
Inventories — net .....	6,024,266	6,579,235
Prepaid expenses and other current assets .....	1,726,778	1,813,133
Assets held for sale .....	—	1,505,658
Total current assets .....	32,639,087	30,122,635
PROPERTY AND EQUIPMENT — net .....	9,691,686	8,116,177
PURCHASED TECHNOLOGY RIGHTS — net .....	3,031,613	3,510,288
GOODWILL — net .....	6,930,192	6,930,192
TRADEMARKS AND OTHER INTANGIBLE ASSETS — net .....	12,652,564	13,023,566
OTHER ASSETS .....	473,095	405,785
<b>TOTAL ASSETS</b> .....	<b>\$ 65,418,237</b>	<b>\$ 62,108,643</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable .....	\$ 5,397,213	\$ 4,159,242
Accrued liabilities .....	3,717,630	2,620,913
Short-term borrowings .....	154,335	—
Deferred revenue and deferred gain on sale leaseback .....	221,726	223,524
Current portion of long-term debt and capital lease obligations .....	323,758	343,403
Liabilities related to assets held for sale .....	—	233,446
Total current liabilities .....	9,814,662	7,580,528
Deferred revenue and deferred gain on sale leaseback .....	553,486	650,212
Long-term debt and capital lease obligations — net of current portion .....	3,328,139	3,649,733
Total liabilities .....	13,696,287	11,880,473
<b>COMMITMENTS AND CONTINGENCIES (Note 17)</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Preferred stock — Series B, \$.001 par value — 2,500,000 shares authorized, 100,000 shares issued and outstanding .....	462,500	462,500
Common stock, \$.001 par value — 65,000,000 shares authorized, 45,864,050 shares and 45,723,296 shares issued and outstanding .....	45,864	45,723
Capital in excess of par value .....	84,372,257	83,968,913
Accumulated other comprehensive loss .....	(63,924)	(73,453)
Accumulated deficit .....	(32,543,676)	(33,604,140)
Common stock in treasury, at cost, 218,411 shares and 225,100 shares ..	(551,071)	(571,373)
Total shareholders' equity .....	51,721,950	50,228,170
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b> .....	<b>\$ 65,418,237</b>	<b>\$ 62,108,643</b>

The accompany notes are an integral part of these consolidated financial statements.

**ZILA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**Years Ended July 31, 2005, 2004 and 2003**

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net revenues .....	\$44,324,845	\$41,404,805	\$39,210,412
Cost of products sold .....	<u>15,385,266</u>	<u>16,120,121</u>	<u>16,772,674</u>
Gross profit .....	28,939,579	25,284,684	22,437,738
Operating costs and expenses:			
Marketing and selling .....	15,938,675	9,552,462	7,224,855
General and administrative .....	11,537,357	11,149,629	10,362,767
Severance and related charges .....	191,957	349,533	1,322,147
Other operating costs .....	296,118	—	—
Research and development .....	7,181,206	5,932,870	4,137,215
Impairment of assets .....	—	288,940	140,794
Depreciation and amortization .....	<u>2,688,141</u>	<u>2,482,514</u>	<u>2,346,315</u>
	<u>37,833,454</u>	<u>29,755,948</u>	<u>25,534,093</u>
Loss from operations .....	<u>(8,893,875)</u>	<u>(4,471,264)</u>	<u>(3,096,355)</u>
Other income (expense):			
Interest income .....	187,712	109,245	15,132
Interest expense .....	(195,508)	(342,114)	(389,628)
Contract settlement gain, net of related expense .....	—	—	14,844,093
Gain on sale of assets .....	(6,202)	470,462	530,756
Other expense .....	<u>(114,017)</u>	<u>(138,727)</u>	<u>(105,249)</u>
	<u>(128,015)</u>	<u>98,866</u>	<u>14,895,104</u>
Income (loss) from continuing operations before income taxes and accounting change .....	(9,021,890)	(4,372,398)	11,798,749
Income tax expense .....	<u>(8,300)</u>	<u>(2,106)</u>	<u>(188,126)</u>
Income (loss) from continuing operations before accounting change ..	<u>(9,030,190)</u>	<u>(4,374,504)</u>	<u>11,610,623</u>
Discontinued operations:			
Income (loss) from operations .....	426,625	37,693	(251,071)
Net gain on disposal .....	9,781,029	—	10,000
Income tax expense .....	<u>(78,000)</u>	<u>—</u>	<u>—</u>
Income (loss) from discontinued operations .....	<u>10,129,654</u>	<u>37,693</u>	<u>(241,071)</u>
Income (loss) before accounting change .....	1,099,464	(4,336,811)	11,369,552
Cumulative effect of accounting change .....	—	—	(4,084,193)
Net income (loss) .....	1,099,464	(4,336,811)	7,285,359
Preferred stock dividends .....	39,000	39,000	39,000
Net income (loss) attributable to common shareholders .....	<u>\$ 1,060,464</u>	<u>\$ (4,375,811)</u>	<u>\$ 7,246,359</u>
Basic net income (loss) per common share:			
Income (loss) from continuing operations .....	\$ (0.20)	\$ (0.10)	\$ 0.26
Income (loss) from discontinued operations .....	0.22	—	(0.01)
Accounting change .....	—	—	(0.09)
Net income (loss) .....	<u>\$ 0.02</u>	<u>\$ (0.10)</u>	<u>\$ 0.16</u>
Weighted average shares outstanding .....	<u>45,564,562</u>	<u>45,333,794</u>	<u>45,115,111</u>
Diluted net income (loss) per common share:			
Income (loss) from continuing operations .....	\$ (0.20)	\$ (0.10)	\$ 0.26
Income (loss) from discontinued operations .....	0.22	—	(0.01)
Accounting change .....	—	—	(0.09)
Net income (loss) .....	<u>\$ 0.02</u>	<u>\$ (0.10)</u>	<u>\$ 0.16</u>
Weighted average shares outstanding .....	<u>45,564,562</u>	<u>45,333,794</u>	<u>45,390,939</u>

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

**ZILA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**  
**Years Ended July 31, 2005, 2004 and 2003**

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net income (loss) .....	\$1,099,464	\$(4,336,811)	\$7,285,359
Other comprehensive income (loss)			
Foreign currency translation adjustment .....	<u>9,529</u>	<u>2,191</u>	<u>(268)</u>
Comprehensive income (loss) .....	<u>\$1,108,993</u>	<u>\$(4,334,620)</u>	<u>\$7,285,091</u>
		<u>Foreign Currency Translation Adjustments</u>	<u>Accumulated Other Comprehensive Loss</u>
Balance at July 31, 2003 .....		\$(75,644)	\$(75,644)
Other comprehensive income .....		<u>2,191</u>	<u>2,191</u>
Balance at July 31, 2004 .....		(73,453)	(73,453)
Other comprehensive income .....		<u>9,529</u>	<u>9,529</u>
Balance at July 31, 2005 .....		<u>\$(63,924)</u>	<u>\$(63,924)</u>

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

**ZILA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**Years Ended July 31, 2005, 2004 and 2003**

	Shareholders' Equity								
	Preferred Stock		Common Stock		Capital in Excess of Par Value	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
	Shares	Amount	Shares	Par Value					
BALANCE, JULY 31, 2002 .....	100,000	\$462,500	45,291,160	\$45,291	\$82,900,342	\$(36,474,688)	\$(535,120)	\$(75,376)	\$46,322,949
Warrants issued for services provided .....					70,569				70,569
Dividends on preferred stock Purchase of common stock for treasury .....						(39,000)			(39,000)
Issuance of common stock under employee stock purchase plan .....			143,733	144	139,377		(36,253)		(36,253)
Exercise of common stock options and warrants .....			5,000	5	5,245				5,250
Foreign currency translation Net income .....								(268)	(268)
						7,285,359			7,285,359
BALANCE, JULY 31, 2003 .....	100,000	462,500	45,439,893	45,440	83,115,533	(29,228,329)	(571,373)	(75,644)	53,748,127
Warrants issued for services provided .....					28,028				28,028
Dividends on preferred stock Issuance of common stock under employee stock purchase plan .....			76,803	77	249,883				249,960
Exercise of common stock options and warrants .....			206,600	206	440,001				440,207
Trylon shares adjustment to market value .....					135,468				135,468
Foreign currency translation Net loss .....								2,191	2,191
						(4,336,811)			(4,336,811)
BALANCE, JULY 31, 2004 .....	100,000	462,500	45,723,296	45,723	83,968,913	(33,604,140)	(571,373)	(73,453)	50,228,170
Dividends on preferred stock Issuance of common stock under employee stock purchase plan .....			66,519	67	223,017				223,084
Exercise of common stock options and warrants .....			74,235	74	127,882				127,956
Issuance of common stock from treasury .....					3,445		20,302		23,747
Trylon shares adjustment to market value .....					49,000				49,000
Foreign currency translation Net income .....								9,529	9,529
						1,099,464			1,099,464
BALANCE, JULY 31, 2005 .....	<u>100,000</u>	<u>\$462,500</u>	<u>45,864,050</u>	<u>\$45,864</u>	<u>\$84,372,257</u>	<u>\$(32,543,676)</u>	<u>\$(551,071)</u>	<u>\$(63,924)</u>	<u>\$51,721,950</u>

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

**ZILA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**Years Ended July 31, 2005, 2004, 2003**

	<u>2005</u>	<u>2004</u>	<u>2003</u>
<b>OPERATING ACTIVITIES:</b>			
Net income (loss) .....	\$ 1,099,464	\$ (4,336,811)	\$ 7,285,359
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization continuing operations ...	2,688,141	2,482,514	2,346,315
Depreciation and amortization discontinued operations ..	57,345	188,426	70,270
Effect of change in accounting principle .....	—	—	4,084,193
Amortization of deferred financing costs .....	36,418	186,086	183,519
Gain on sale of assets .....	—	(470,462)	(530,756)
Gain from sale of discontinued operations .....	(9,781,029)	—	(10,000)
Impairment of assets .....	—	288,940	140,794
Noncash research and development expense .....	49,000	72,187	—
Noncash stock-based compensation expense .....	42,860	65,827	18,191
Warrants issued for services .....	—	—	70,569
Other .....	(1,710)	(23,400)	(66,873)
Change in assets and liabilities:			
Receivables — net .....	(3,395,402)	(1,272,570)	(1,417,526)
Inventories .....	(200,796)	1,268,369	586,216
Prepaid expenses and other assets .....	68,567	1,576,773	(1,912,060)
Accounts payable and accrued liabilities .....	<u>1,949,787</u>	<u>(3,654,487)</u>	<u>4,100,271</u>
Net cash provided by (used in) operating activities ..	<u>(7,387,355)</u>	<u>(3,628,608)</u>	<u>14,948,482</u>
<b>INVESTING ACTIVITIES:</b>			
Additions to property and equipment .....	(1,871,230)	(1,276,811)	(932,396)
Additions to intangible assets .....	(553,122)	(723,967)	(195,815)
Net proceeds from sale of assets .....	500	1,721,876	531,966
Net proceeds from disposition of discontinued operations ..	11,022,608	—	10,000
Proceeds from sale of short-term investments .....	8,000,000	3,950,000	—
Purchases of short-term investments .....	—	(11,950,000)	—
Restricted cash deposited to collateralize letter of credit ..	<u>(10,430)</u>	<u>(517,353)</u>	<u>—</u>
Net cash provided by (used in) investing activities ...	<u>16,588,326</u>	<u>(8,796,255)</u>	<u>(586,245)</u>
<b>FINANCING ACTIVITIES:</b>			
Net (repayments) proceeds from short-term borrowings ..	154,335	(154,793)	55,009
Proceeds from issuance of common stock .....	317,580	652,757	126,561
Acquisition of treasury stock .....	—	—	(36,253)
Dividends paid to preferred stockholders .....	(68,250)	(19,500)	(49,000)
Financing costs .....	—	(91,531)	(18,206)
Proceeds from long-term borrowings .....	—	—	641,515
Principal payments on long-term debt .....	<u>(347,034)</u>	<u>(442,639)</u>	<u>(525,584)</u>
Net cash provided by (used in) financing activities ..	<u>56,631</u>	<u>(55,706)</u>	<u>194,042</u>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS .....</b>	<b>9,257,602</b>	<b>(12,480,569)</b>	<b>14,556,279</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR .....</b>	<b><u>3,679,915</u></b>	<b><u>16,160,484</u></b>	<b><u>1,604,205</u></b>
<b>CASH AND CASH EQUIVALENTS, END OF YEAR ..</b>	<b><u>\$12,937,517</u></b>	<b><u>\$ 3,679,915</u></b>	<b><u>\$16,160,484</u></b>

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

**ZILA, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**Years Ended July 31, 2005, 2004 and 2003**

**1. Nature of Business Activities and Summary of Significant Accounting Policies**

*Nature of Business Activities*

Zila, Inc. and subsidiaries ("Zila"), a Delaware corporation, is an innovator in preventive healthcare technologies and products, focusing on enhanced body defense and the detection of pre-disease states.

Our business is organized into the following Business Units: Nutraceuticals, Pharmaceuticals and Biotechnology. The Nutraceuticals Business Unit includes Zila Nutraceuticals, Inc., a manufacturer and marketer of *Advanced Protection Ester-C*<sup>®</sup> and *Ester-E*<sup>®</sup>, proprietary, branded, highly effective forms of vitamin C and vitamin E. The Zila Pharmaceuticals Business Unit includes Zila Pharmaceuticals, Inc. and the *ViziLite*<sup>®</sup> chemiluminescent disposable light product for illumination of oral mucosal abnormalities, *Peridex*<sup>®</sup> prescription periodontal rinse, the plastic molded products of Zila Swab Technologies, Inc., dba *Innovative*<sup>®</sup> Swab Technologies ("IST"), and the *Zilactin*<sup>®</sup> family of products which was sold on June 27, 2005 as more fully described in Note 3. The Zila Biotechnology Business Unit includes Zila Biotechnology Inc., Zila Technical, Inc., and Zila Limited, and is the research, development and licensing business specializing in pre-cancer/cancer detection through its patented *Zila*<sup>®</sup> Tolonium Chloride and *OraTest*<sup>®</sup> technologies and now manages the *OraTest*<sup>®</sup> product, an oral cancer diagnostic system.

On January 1, 2005, Oxycal Laboratories, Inc. ("Oxycal") was renamed Zila Nutraceuticals, Inc. after the merger with its wholly-owned subsidiary, Zila Nutraceuticals, Inc.

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("generally accepted accounting principles").

*Summary of Significant Accounting Policies*

*Principles of Consolidation* — The consolidated financial statements include the accounts of Zila, Inc. and its wholly-owned subsidiaries, Zila Nutraceuticals, Inc., Zila Pharmaceuticals, Inc., Zila Biotechnology, Inc., Zila Limited., Bio-Dental Technologies Corporation ("Bio-Dental"), Zila Technical, Inc., Zila Technologies, Inc., and Zila Swab Technologies, Inc. Bio-Dental is inactive and has no operations. All significant intercompany balances and transactions are eliminated in consolidation.

*Use of Estimates and Risks and Uncertainties* — The preparation of financial statements in conformity with generally accepted accounting principles necessarily requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates based upon future events, which could include, among other risks, changes in the regulations governing the manner in which we sell our products, changes in the health care environment, and reliance on contract manufacturing services. Significant use of estimates include: (i) useful lives of intangibles; (ii) impairment analyses; (iii) depreciable lives of assets; (iv) income tax valuation allowances; (v) contingency and litigation reserves; (vi) inventory valuation; and (vii) allowances for accounts receivable, cash discounts, sales incentives and sales returns.

In our Biotechnology Business Unit, the cash flows used to measure long-lived assets related to the *OraTest*<sup>®</sup> product are dependent upon obtaining FDA approval and generating sufficient revenues from sales of the *OraTest*<sup>®</sup> product. The rigorous clinical testing and an extensive regulatory approval process mandated by the FDA and equivalent foreign authorities before any new drug can be marketed can take a number of years and require the expenditure of substantial resources. We anticipate that our current cash and cash equivalents, along with cash generated from our Nutraceuticals and Pharmaceuticals groups, and the availability of cash under our line of credit will be adequate to support these activities. However, obtaining such approvals and completing such testing is a costly and time-consuming process, and approval may not be ultimately obtained. The length of the FDA review period varies considerably, as does the amount of clinical

## ZILA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

data required to demonstrate the safety and efficacy of a specific product. Net long-lived assets related to the OraTest® product as of July 31, 2005 of \$6.3 million have been capitalized.

*Reclassifications* — For comparative purposes, certain prior year amounts were reclassified to conform to current year presentation.

*Revisions* — We revised certain prior period amounts to conform to the current period presentation. Auction rate securities in an amount of \$8.0 million have been reclassified from cash and cash equivalents to short-term investments in the July 31, 2004 consolidated balance sheets to conform to the fiscal 2005 financial statement presentation. Additionally, approximately \$917,000 and \$825,000 related to management fees paid to Omnii were reclassified from marketing and selling costs to revenue for fiscal 2004 and 2003, respectively. Cash flows of \$517,000 related to the funding of the restricted cash account with Wells Fargo were reclassified to investing rather than financing cash flows in the statement of cash flows for fiscal 2004. We do not believe that these revisions are material to the consolidated financial statements.

*Business Concentration* — We extend credit on a non-collateralized basis primarily to manufacturing companies and wholesale distributors in the United States, Canada and 18 other foreign countries. We perform periodic credit evaluations of our customer's financial condition in our decision to provide credit terms. We estimate the level of accounts receivable which will ultimately not be paid. Historically, we have not experienced significant credit losses. For each of the last three fiscal years, there have been sales to significant customers. Sales to these significant customers as a percent of net revenues were 58% (three customers), 57% (four customers), and 43% (four customers) in fiscal years 2005, 2004 and 2003, respectively. As of July 31, 2005, accounts receivable due from our three significant customers represented 49% of our consolidated accounts receivable.

Our cash and cash equivalents are maintained with financial institutions with high credit standings. However, our balances at these financial institutions exceed federally insured limits.

*Revenue Recognition* — Revenue from sales of products is recognized when earned; that is, when the risks and rewards of ownership have transferred to the customer, which is considered to have occurred when delivery to the designated location or carrier has occurred. Cash discounts, sales incentives, and returns are estimated and recognized at the time of sale based upon historical activity and current customer commitments.

On occasion, we enter into arrangements to license our technology on specifically approved products. For those arrangements where we have continuing involvement with the licensee, nonrefundable, upfront license fees are recognized systematically as they are earned over the life of the agreement. Fees associated with substantive, at risk, performance milestones are recognized as revenue as the milestones are achieved, as defined in the respective agreements. For perpetual licenses or manufacturing rights agreements, where (i) we have no further continuing involvement with the licensee; (ii) the fees are nonrefundable; and (iii) the fees are not a prepayment of future royalties, the fees are recognized as revenue at the time the arrangement becomes effective.

*Cash and Cash Equivalents* — Cash equivalents include highly liquid investments purchased with remaining maturities of three months or less.

*Restricted Cash* — Under the terms of our Replacement Letter of Credit agreement as more fully described in Note 10, we are required to maintain an interest bearing cash collateral account representing the difference between the replacement letter of credit amount and the maximum commitment amount, as defined. These funds are maintained in highly liquid investments with remaining maturities of three months or less.

*Allowances for Doubtful Accounts and Sales Returns* — We provide for an allowance for doubtful accounts based on historical experience and a review of our accounts receivable. Receivables are presented net



## ZILA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

of allowances for doubtful accounts and for sales returns of \$150,000 at July 31, 2005 and \$272,000 at July 31, 2004. We evaluate these estimates on a monthly basis and revise them as necessary.

*Inventories* consist of finished goods, work in process and raw materials and are stated at the lower of cost (first-in, first-out method) or market.

*Property and Equipment* are stated at cost and are depreciated using the straight-line method over their respective estimated useful lives, ranging from 3 to 40 years. Leasehold improvements and capital leased assets are depreciated over the lease term or the estimated useful life, whichever is shorter.

Listed below are the ranges of useful lives by property and equipment category:

Building .....	40 years
Building improvements .....	15 years
Leasehold improvements .....	5-7 years
Furniture and equipment .....	3-7 years
Production, laboratory and warehouse equipment .....	7-10 years

*Long-Lived Assets and Long-Lived Assets to be Disposed of* — Our policy is to review the carrying value of long-lived assets to be held and used and long-lived assets to be disposed of, including intangibles with estimated useful lives, under the provisions of SFAS No. 144 and its related interpretations, whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An evaluation of recoverability is performed using such information as the estimated future undiscounted cash flows associated with the asset compared to the asset's carrying value, the work of specialists, and other available information to determine if impairment exists. An impairment loss is measured as the difference between the carrying amount and the fair value of the impaired asset and is recognized as a charge against current operations. If an impairment exists, the remaining amortization period for the impaired asset would be reassessed and revised if necessary.

In fiscal years 2004 and 2003, asset impairment charges of approximately \$289,000 and \$141,000, respectively, were recorded related to the write down of: (i) fixtures, equipment, patents and trademarks of IST; and (ii) a mold and certain intangible assets related to the Pro-Ties™ product line. The expected future cash flows for each of these assets were used to determine the amount of impairment. The charges are included in the Pharmaceuticals reporting segment.

*Goodwill and Other Intangible Assets* — As of August 1, 2002, we adopted SFAS No. 142, "Goodwill and Other Intangible Assets." Under the requirements of this SFAS, goodwill is no longer amortized but rather assessed at least annually for impairment using a fair value approach. Our policy is to test goodwill for impairment annually as of May 1, the first day of our fourth fiscal quarter. During the quarter ended April 30, 2005, we changed the date of our annual goodwill impairment test from April 30, the last day of our third fiscal quarter. We selected this date to perform our annual goodwill impairment test because we believe that such date better aligns with our annual planning and budgeting process, providing efficiencies and savings in professional fees. We believe that the change will not delay, accelerate or avoid an impairment charge. Accordingly, we believe that the accounting change described above is to an alternative date which is preferable.

We completed our fiscal 2005 assessment in our fourth quarter and determined that there was no goodwill impairment. Upon adoption of SFAS No. 142 as of August 1, 2002, we completed the transitional goodwill impairment test for our reporting units and recorded a charge of \$4,084,000 related to our Pharmaceuticals Business Unit.

We amortize the cost of other intangibles over their estimated useful lives unless such lives are deemed indefinite. We continually evaluate the reasonableness of the estimated useful lives of amortizable intangibles.

## ZILA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Our policy is to review the carrying amounts of intangible assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Such events or circumstances might include a significant decline in market share, a significant decline in profits, rapid changes in technology, significant litigation or other items. In evaluating the recoverability of other intangible assets, our policy is to compare the carrying amounts of such assets with the estimated undiscounted future operating cash flows. In the event impairment exists, an impairment charge would be determined by comparing the carrying amounts of the asset to the applicable estimated future cash flows, discounted at a risk-adjusted rate. In addition, the remaining amortization period for the impaired asset would be reassessed and revised if necessary.

The components of goodwill at July 31, 2005 are as follows:

*Pharmaceuticals Goodwill* — Goodwill totaling approximately \$4.0 million (net of accumulated amortization of \$4.6 million) related to the Peridex<sup>®</sup> product which was acquired from The Procter & Gamble Company in November 1997.

*Zila Nutraceuticals* — Goodwill totaling approximately \$2.9 million (net of accumulated amortization of \$890,000) is related to the Ester-C<sup>®</sup> group of products which were acquired in 1997.

Significant components of intangible assets at July 31, 2005 are as follows:

*Purchased Technology Rights* — In 1996, we acquired CTM Associates, Inc. (“CTM”). The purchase of CTM perfected our interest in the OraTest<sup>®</sup> technology and eliminated our obligation to pay royalties to CTM on future sales of the OraTest<sup>®</sup> product. The recoverability of the \$3.0 million net purchased technology rights is dependent upon obtaining FDA approval and generating sufficient revenues from future sales of the OraTest<sup>®</sup> products. Fixed assets of approximately \$1.2 million (primarily related to our manufacturing facility), patents and patents pending of \$1.6 million and inventory, drug substance and related components of \$482,000 are also associated with the OraTest<sup>®</sup> products and are grouped with the purchased technology rights for the purpose of testing recoverability. The purchased technology rights are amortized on a straight-line basis over the expected period of benefit, which was based on the estimated remaining life of the related patents, which will expire in 2011.

*Trademarks and Other Intangible Assets* — Trademarks are amortized on a straight-line basis over the lesser of their legal or expected lives, which range from 8 to 30 years. Other intangible assets include deferred patent costs, which represent legal costs associated with filing patent applications, and licensing costs related primarily to the ViziLite<sup>®</sup> and Ester-E<sup>®</sup> products. Other intangible assets are amortized on a straight-line basis over the lesser of their legal or expected lives, which range from 4 to 17 years.

*Research and Development* — The costs associated with research and development programs for new products and significant product improvements are expensed as incurred. Research and development costs totaled \$7,181,000, \$5,933,000 and \$4,137,000 in fiscal 2005, 2004 and 2003, respectively.

*Stock Options* — At July 31, 2005, we had two stock-based employee and director’s compensation plans, which are more fully described in Note 10. We apply Accounting Principles Board (“APB”) Opinion No. 25 and related interpretations in accounting for our stock-based employee compensation plans and the director’s stock option plan. Accordingly, no compensation cost has been recognized for stock-based employee and director compensation plans. Had compensation cost been computed based on the fair value of awards on the date of grant, utilizing the Black-Scholes option-pricing model, consistent with the method stipulated by SFAS No. 123, and calculated on a straight-line basis over the requisite service period, pro forma net income (loss) attributable to common shareholders and income (loss) per share attributable to common shareholders

**ZILA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

for the fiscal years ended July 31, 2005, 2004 and 2003 would have been reported as follows (in thousands, except per share amounts):

	Fiscal Years Ended July 31,		
	2005	2004	2003
Net income (loss) attributable to common shareholders:			
As reported .....	\$ 1,060	\$(4,376)	\$7,246
Add: Compensation expense for equity awards recorded at fair value included in the determination of net income (loss) as reported .....	43	66	18
Less: Compensation expense for equity awards determined by the fair value based method .....	<u>3,915</u>	<u>1,079</u>	<u>321</u>
Pro forma .....	<u><u>\$(2,812)</u></u>	<u><u>\$(5,389)</u></u>	<u><u>\$6,943</u></u>
Net income (loss) attributable to common shareholders per basic share outstanding:			
As reported .....	\$ 0.02	\$ (0.10)	\$ 0.16
Pro forma .....	\$ (0.06)	\$ (0.12)	\$ 0.15
Net income (loss) attributable to common shareholders per diluted share outstanding:			
As reported .....	\$ 0.02	\$ (0.10)	\$ 0.16
Pro form .....	\$ (0.06)	\$ (0.12)	\$ 0.15

The weighted-average grant-date fair value of options granted during the years ended July 31, 2005, 2004 and 2003 was \$2,807,000, \$1,817,000 and \$583,000, respectively. The value of options is estimated on the date of grant using the following weighted average assumptions:

	Fiscal Years Ended July 31,		
	2005	2004	2003
Black-Scholes model assumptions:			
Risk-free interest rate .....	4%	4%	3%
Expected volatility .....	75%	75%	80%
Expected term (in years) .....	6.4	5.7	5.6
Dividend yield .....	0%	0%	0%

Noncash stock compensation expense related to stock awards and stock issuances under our employee stock purchase plan was \$43,000, \$66,000 and \$18,000 in fiscal 2005, 2004 and 2003, respectively.

*Net Income (Loss) Per Common Share* — Basic net income (loss) per common share is computed by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the year before giving effect to stock options and warrants considered to be dilutive common stock equivalents. Diluted net income (loss) per common share is computed by dividing net income (loss) available to common shareholders by the weighted average number of common and potentially dilutive shares outstanding during the year after giving effect to convertible preferred stock, stock options and warrants. For the year ended July 31, 2005 and 2004, the effect of 482,000 and 874,000 shares, respectively, of convertible preferred stock, options and warrants were excluded because their inclusion would have had an anti-dilutive effect on earnings per share.

**ZILA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

For the year ended July 31, 2003, the following is a reconciliation of the numerators and denominators of basic and diluted per share computations for income from continuing operations (in thousands, except per share amounts):

Income attributable to common shareholders .....	<u>\$ 7,246</u>
Average outstanding common shares .....	45,115
Effect of dilutive securities:	
Options .....	162
Warrants .....	14
Convertible preferred stock .....	<u>100</u>
Average outstanding and potentially dilutive common shares .....	<u>45,391</u>
Basic income .....	\$ 0.16
Diluted income .....	\$ 0.16

*Financial Instruments* — The carrying amounts and estimated fair value of our financial instruments are as follows:

The carrying values of cash and cash equivalents, restricted cash, receivables, accounts payable and accrued expenses approximate fair values due to the short-term maturities of these instruments.

The carrying amount of long-term debt and short-term borrowings are estimated to approximate fair value as the actual interest rate is consistent with the rate estimated to be currently available for debt of similar term and remaining maturity.

Financial instruments, which potentially subject us to credit risk, consist principally of trade receivables. In the normal course of business, we provide credit primarily to pharmaceutical wholesalers and nutraceutical manufacturers. Ongoing credit evaluations are performed of customers to determine an appropriate allowance for credit losses.

Estimates of fair value are subjective in nature and involve uncertainties and significant matters of judgment and do not include tax considerations. Therefore, results cannot be determined with precision and cannot be substantiated by comparison to independent market values and may not be realized in actual sale or settlement of the instruments. There may be inherent weaknesses in any calculation technique, and changes in the underlying assumptions could significantly affect the results.

*Comprehensive Income* consists of net income (loss) and other gains and losses affecting shareholders' equity that, under generally accepted accounting principles are excluded from net income (loss). Such items consist primarily of foreign currency translation gains and losses.

*Advertising* — We advertise primarily through television, radio and print media. Our policy is to expense advertising costs, including production costs, as incurred. These costs are included in marketing and selling expenses.

*Shipping Costs* — Costs of shipping products to customers are included in cost of products sold.

*Recently Issued Accounting Pronouncements* — In June 2005, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 154, "Accounting Changes and Error Corrections" ("SFAS No. 154"), a replacement of APB Opinion No. 20, "Accounting Changes" and FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements." SFAS No. 154 applies to all voluntary changes in accounting principle and changes the requirements for accounting for and reporting a change in accounting principle. SFAS No. 154 requires the retrospective application to prior periods' financial statements of the direct effect of a voluntary change in accounting principle unless it is impracticable.

## ZILA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

APB No. 20 required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. The FASB stated that SFAS No. 154 improves financial reporting because its requirements enhance the consistency of financial information between periods. Unless early adoption is elected, SFAS No. 154 is effective for fiscal years beginning after December 15, 2005. Early adoption is permitted for fiscal years beginning after June 1, 2005. SFAS No. 154 does not change the transition provisions of any existing accounting pronouncements, including those that are in a transition phase as of the effective date of this statement. We will adopt SFAS No. 154 on August 1, 2005, the beginning of our next fiscal year.

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R is a revision of FASB Statement No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123") and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and its related implementation guidance. As permitted under SFAS No. 123, we currently account for stock options under APB Opinion No. 25 whereby (i) stock options are granted at market price and (ii) no compensation expense is recognized since the exercise price equals the stock price on the grant date, and we disclose the pro forma effect on net earnings assuming that compensation cost had been recognized under the requirements of SFAS No. 123. SFAS No. 123R requires companies to measure and recognize compensation expense for all stock-based payments at fair value. Stock-based payments include stock option grants. We grant options to purchase common stock to some of our employees and directors at prices equal to the market value of the stock on the dates the options were granted. SFAS No. 123R becomes effective for us beginning August 1, 2005, the beginning of our next fiscal year. SFAS No. 123R permits public companies to adopt its requirements using one of two methods: (i) a "modified prospective" method in which the requirements of SFAS No. 123R apply for all share-based payments granted or modified after the effective date, and to any unvested awards as service is rendered on or after the effective date or (ii) a "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits companies to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either for all periods presented or prior interim periods of the year of adoption. We will adopt SFAS No. 123R using the modified prospective method and expect the adoption of this standard will have an unfavorable impact on our consolidated results of operations and net income per common share. Note 1 — *Stock Options* illustrates the pro forma effects on net income and earnings per share as if we had adopted SFAS No. 123 using the Black-Scholes option-pricing model. However, the impact on future periods will depend on, among other things, the number of share-based awards granted and variables such as the volatility of our stock and when employees exercise stock options.

On March 3, 2005 our Board of Directors approved the immediate vesting of all outstanding and unvested stock options previously granted under our Stock Award Plan to officers and employees, for which the option exercise price was above the closing price for our common stock on April 29, 2005. On such date, the closing price was \$3.09. Options held by non-employee directors were excluded from this acceleration. The immediate vesting of these options will avoid the compensation expense in future periods on these options which were granted prior to the implementation of SFAS No. 123R.

In December 2004, the FASB issued FASB Staff Position No. FAS 109-1, "Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004 (AJCA)." The AJCA was signed into law in October 2004 and includes a tax deduction of up to 9 percent (when fully phased in) of the lesser of (i) "qualified production activities income" as defined in the Act, or (ii) taxable income (after the deduction for domestic manufacturing) from this legislation should be accounted for as a "special deduction" instead of a tax rate reduction. We will be able to start claiming this deduction in our fiscal 2006. We expect that the adoption of SFAS No. 109-1 will not have a material impact on our financial position or results of operations.

## ZILA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In November 2004, the FASB issued Statement of Financial Accounting Standards No. 151 "Inventory Costs — an amendment of ARB No. 43, Chapter 4" ("SFAS No. 151") effective for fiscal years beginning after June 15, 2005. SFAS No. 151 will become effective for us on August 1, 2005, the beginning of our next fiscal year. This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). This Statement requires that those items be recognized as current-period charges. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. We believe that the adoption of SFAS No. 151 will not have a material effect on our financial position or results of operations.

#### 2. ViziLite® Acquisition

On December 4, 2001, we acquired the world marketing and distribution rights (excluding the Pacific Rim) for the FDA cleared ViziLite® chemiluminescent light technology from The Trylon Corporation ("Trylon") of Torrance, California. The rights acquired include the FDA-approved devices and methods of conducting endoscopic examinations of certain body cavities using chemiluminescent light sources.

In payment of the purchase price for the transaction, 2,000,000 shares of restricted common stock were issued, of which 1,625,000 shares were delivered to Trylon and 375,000 shares were placed into escrow. The shares of common stock are restricted in accordance with the following provisions: (i) all 2,000,000 shares are restricted within the meaning of Rule 144 under the Securities Act of 1933, as amended; (ii) 500,000 of the shares delivered to Trylon had an additional contractual restriction upon sale or transfer that will be removed at the earlier of ten years following the closing date or the achievement of certain future sales milestones of the ViziLite® product; and (iii) 375,000 of the other shares delivered to Trylon had an additional contractual restriction that will be removed at the earlier of ten years following the closing date or in the event of the submission of a new 510(k) application with the FDA for a new product line extension of the ViziLite® product then under development. The 375,000 shares in escrow were to remain in escrow until the date upon which FDA marketing clearance is received on the new product line extension of the ViziLite® product described in item (iii) above. If such clearance is not received on or before the second anniversary of the closing date, the stock in escrow is to be returned to us and cancelled, subject to certain exceptions.

The 1,625,000 shares of restricted common stock that were delivered were valued at \$2,947,000 as follows: (i) the fair value of the 750,000 shares restricted within the meaning of Rule 144 but not otherwise restricted, were valued at \$1,853,000, which was based upon the common stock share market price of \$2.47 on December 4, 2001; (ii) the 500,000 shares of restricted common stock subject to additional contractual restrictions relating to sales milestones were valued at \$621,000 and were discounted from the December 4, 2001 share price based upon the length of time and probability of achieving the requisite sales milestones; and (iii) the 375,000 restricted shares of common stock subject to additional contractual restrictions tied to FDA submissions were valued at \$473,000 and were discounted based upon the length of time and probability of submitting an acceptable 510(k) application to the FDA. The \$2,474,000 of value referenced in items (i) and (ii) above was recorded as an intangible asset as a license. The \$473,000 in value referenced in item (iii) above was recorded as research and development and expensed.

On October 15, 2003, we completed an agreement that was the result of a mediated settlement with Trylon. As part of the settlement, we agreed that Trylon's royalty rates for net sales of the ViziLite® product would be reduced from 10% to 5% for the first five years, and from 5% to 2.5% for the second five years. Thereafter, the royalty payments end. As part of the settlement, we agreed to eliminate the contractual restrictions relating to sales milestones associated with 500,000 shares of the restricted common stock and instead tie the removal of contractual restrictions on these shares to Trylon's achievement of the product development milestones on the ViziLite® line extension and obtaining the required governmental approvals relating to the product development milestones.

**ZILA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The October 15, 2003 agreement with Trylon was further modified by an agreement dated March 26, 2004. This agreement addressed the timing and requirements for the removal of contractual restrictions and escrow restrictions on the 1,250,000 shares of common stock described above, including the 500,000 restricted shares covered by the October 15, 2003 agreement. Upon execution of the March 26, 2004 agreement, we removed the contractual restrictions on 312,500 of the 1,250,000 shares in recognition of the achievement of a milestone. On July 31, 2004, we removed the contractual restrictions on another 312,500 shares of stock in exchange for receiving the right to obtain from Trylon either direct ownership or a royalty-free license of the ViziLite® product line extension subject to the 510(k) application pending with the FDA. Trylon's rights to the 375,000 shares held in escrow expired on June 30, 2004, and the shares were returned to us for cancellation. Contractual restrictions on 250,000 shares were removed on January 31, 2005, upon Trylon's obtaining the required governmental approvals relating to the product development milestone. No restrictions remain on the Trylon shares.

As a result of the release of restrictions on March 26, 2004 and January 31, 2005, we recorded non-cash charges to research and development of \$72,200 and \$49,000, respectively, reflecting the estimated difference in the fair market value of these shares with and without restrictions. With respect to the acquisition of the technology rights to the ViziLite® product line extension on July 31, 2004, we recorded an intangible asset of \$63,200.

On June 1, 2005, Trylon's rights, titles and interests under its agreements with us were acquired by Shared Medical Resources, LLC.

**3. Discontinued Operation**

On June 27, 2005, our subsidiary, Zila Pharmaceuticals, Inc., sold substantially all of the assets of its Zilactin® brand over-the-counter lip and oral care products to Blairex Laboratories, Inc., an Indiana corporation. We received approximately \$11.0 million in cash and we retained trade accounts receivable of \$895,000 and accounts payable and accrued liabilities of \$1.0 million. The sale resulted in a pre-tax gain of \$9.8 million. The sale of Zilactin® was made as part of our strategy of concentrating our business on preventive healthcare technologies and products focusing on enhanced body defense and the detection of pre-disease states.

The Zilactin® product line meets the definition of a "component of an entity" and has been accounted for as a discontinued operation under SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." The results of operations for Zilactin® have been classified as discontinued operations in all periods presented.

The results of the Zilactin® discontinued operation are as follows (in thousands):

	Fiscal Years Ended July 31,		
	2005	2004	2003
Net revenues .....	\$6,398	\$7,106	\$7,071
Income (loss) from operations .....	\$ 427	\$ 38	\$(251)

**4. Assets Held for Sale**

In March 2004, our Board of Directors authorized the divestiture of the net assets of IST, our plastic molded products manufacturing subsidiary, in order to focus on our core business operations. IST is a reporting unit within our Pharmaceuticals Business Unit. We reclassified all of the assets and related liabilities to "assets held for sale" and "liabilities related to assets held for sale," respectively, and ceased depreciation and amortization of IST's assets.

## ZILA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In September 2004, the Board of Directors reversed the divestiture decision and withdrew IST from the market. Management determined that IST is the best available sourcing option for a new product under development and, therefore, IST's importance to future operations has changed. Further, no acceptable purchase offer resulted from the effort to sell IST. Based on the results of the offer process and in accordance with the requirements of SFAS No. 144, we recognized a non-cash impairment charge of \$289,000 in the fourth quarter of fiscal 2004 to give effect to our revised estimate of the fair value of IST.

Under the requirements of SFAS No. 144, as a result of the decision to retain IST, in our quarter ended October 31, 2004, the "assets held for sale" and "liabilities related to assets held for sale" were reclassified to their original financial statement presentation. If this reclassification were made at July 31, 2004, the net amounts for property, plant and equipment and patents (\$1,243,000) would be presented as long-term assets instead of current assets.

Summarized balance sheet information for IST as of July 31, 2004 is set forth below (in thousands):

Current assets .....	\$ 250
Property, plant and equipment, net .....	1,026
Patents, net .....	217
Other .....	<u>13</u>
Total assets held for sale .....	<u>\$1,506</u>
Current liabilities .....	<u>233</u>
Total liabilities related to assets held for sale .....	<u>\$ 233</u>

#### 5. Sale of Assets

On January 30, 2004, as part of our strategy to employ financial assets in core business competencies, we completed the sale and a five-year leaseback of our corporate headquarters for approximately \$1.7 million in net cash proceeds. We realized a pre-tax gain of \$1.2 million, of which we recognized approximately \$470,000 in the quarter ended January 31, 2004. The \$470,000 gain represents the excess of the net proceeds over the net present value of the future lease payments. The balance of the gain of \$765,000 was deferred and will be amortized on a straight-line basis over the five-year lease term as a reduction of rent expense in general and administrative expenses. The leaseback is accounted for as an operating lease.

On July 30, 2003, we sold our investment in PracticeWares, Inc. ("PracticeWares") for \$525,000. Since no cost basis was assigned to this investment, the entire cash proceeds from this sale were recorded as a pre-tax gain.

#### 6. Gain from Contract Settlement

On April 14, 2003, we reached agreement in a dispute with our former contract research organization and received a \$20 million settlement payment on June 30, 2003. As part of the settlement, we incurred approximately \$5.2 million in legal, consulting and other related obligations, resulting in a net gain of approximately \$14.8 million.



**ZILA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**7. Inventories**

Inventories consist of the following at July 31 (in thousands):

	<u>2005</u>	<u>2004</u>
Finished goods .....	\$ 732	\$2,161
Work in process .....	579	295
Raw materials .....	4,853	4,320
Inventory reserves .....	<u>(140)</u>	<u>(197)</u>
Total inventories .....	<u>\$6,024</u>	<u>\$6,579</u>

**8. Property and Equipment**

Property and equipment consists of the following at July 31 (in thousands):

	<u>2005</u>	<u>2004</u>
Land .....	\$ 403	\$ 403
Building and improvements .....	5,135	4,872
Furniture and equipment .....	2,856	2,306
Leasehold improvements and other assets .....	707	382
Production and warehouse equipment .....	<u>7,821</u>	<u>5,833</u>
Total property and equipment .....	16,922	13,796
Less accumulated depreciation and amortization .....	<u>(7,230)</u>	<u>(5,680)</u>
Property and equipment — net .....	<u>\$ 9,692</u>	<u>\$ 8,116</u>

Depreciation expense related to property and equipment for 2005, 2004 and 2003 for continuing operations was \$1,272,000, \$1,050,000 and \$1,077,000, respectively. Depreciation expense related to property and equipment for 2005, 2004 and 2003 for discontinued operations was \$44,000, \$155,000 and \$37,000, respectively. At July 31, 2005, \$238,000 of assets were required to be capitalized in accordance with SFAS No. 13 "Accounting for Leases." These capital leased assets are included in "furniture and equipment" and "production and warehouse equipment," net of accumulated amortization of \$73,000. Amortization expense related to these capital leased assets was \$45,000.

ZILA, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

9. Intangible Assets

Intangible assets consist of the following at July 31 (in thousands):

	2005			2004		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Amortizable intangibles:						
Purchased technology rights . . . . .	\$ 7,419	\$ 4,387	\$ 3,032	\$ 7,419	\$ 3,909	\$ 3,510
Trademarks and other intangible assets:						
Trademarks . . . . .	11,657	3,602	8,055	11,627	3,119	8,508
Patents . . . . .	3,168	624	2,544	3,189	947	2,242
Licensing costs . . . . .	<u>3,162</u>	<u>1,108</u>	<u>2,054</u>	<u>3,100</u>	<u>826</u>	<u>2,274</u>
Total trademarks and other intangible assets . . . . .	<u>17,987</u>	<u>5,334</u>	<u>12,653</u>	<u>17,916</u>	<u>4,892</u>	<u>13,024</u>
Total amortizable intangible assets . . . . .	<u>25,406</u>	<u>9,721</u>	<u>15,685</u>	<u>25,335</u>	<u>8,801</u>	<u>16,534</u>
Unamortizable intangible asset:						
Goodwill . . . . .	<u>12,401</u>	<u>5,471</u>	<u>6,930</u>	<u>12,401</u>	<u>5,471</u>	<u>6,930</u>
Total intangible assets . . . . .	<u>\$37,807</u>	<u>\$15,192</u>	<u>\$22,615</u>	<u>\$37,736</u>	<u>\$14,272</u>	<u>\$23,464</u>

There was no change in the carrying amount of goodwill for the year July 31, 2005.

In accordance with SFAS No. 142, we discontinued the amortization of goodwill, effective August 1, 2002. We completed the transitional goodwill impairment test for our reporting units and recorded a charge of \$4,084,000 as of August 1, 2002 relating to our Pharmaceutical segment.

Amortization of intangible assets during fiscal 2005, 2004 and 2003 for continuing operations was \$1,416,000, \$1,433,000 and \$1,269,000, and \$14,000, \$33,000 and \$33,000 for discontinued operations, respectively. For fiscal years 2006 through 2010, the amortization of intangibles is estimated to be approximately \$1,500,000 each year.

**ZILA, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**10. Debt**

Debt consisted of the following at July 31 (in thousands):

	<u>2005</u>	<u>2004</u>
Short-term borrowings:		
Installment note payable on insurance policies .....	\$ 154	\$ —
Current portion of long-term debt:		
IDA bond payable, Series A, current portion .....	\$ 245	\$ 245
Capital lease obligations, current portion .....	50	47
Note payable for equipment .....	29	51
Total current portion of long-term debt .....	<u>\$ 324</u>	<u>\$ 343</u>
Long-term debt:		
IDA bond payable, Series A .....	\$2,967	\$3,212
PharmaBio .....	500	500
Capital lease obligations .....	156	201
Notes payable for equipment .....	29	80
Total long-term debt .....	3,652	3,993
Less current portion .....	<u>324</u>	<u>343</u>
Long-term portion .....	<u>\$3,328</u>	<u>\$3,650</u>

On July 31, 2005, we had short-term borrowings of \$154,000 for installments due on certain insurance policies with interest rates from 6.0% to 7.6%.

On February 6, 2004, our subsidiaries, Zila Nutraceuticals, Inc., Zila Pharmaceuticals, Inc., Zila Biotechnology, Inc., and Zila Swab Technologies, Inc., entered into a Credit and Security Agreement (the "Wells Fargo Agreement") with Wells Fargo Business Credit, Inc. ("Wells Fargo") that provides a \$10 million revolving line of credit, effective on August 17, 2004. Borrowings bear interest equal to the prime rate which was 6.25% (Wells Fargo Bank, N.A.) at July 31, 2005. The amount of funds available under the Wells Fargo Agreement is based upon a percentage of the value of eligible receivables and inventory and was \$10.0 million at July 31, 2005. Obligations under the Wells Fargo Agreement are collateralized by various assets, including, but not limited to trade accounts receivable, inventories, equipment and intangible assets. The parent company, Zila, Inc., guarantees the obligations under the Wells Fargo Agreement.

Under the Wells Fargo Agreement, we were required to maintain defined minimum levels of net worth at the end of each fiscal quarter and to limit capital expenditures to \$3.0 million in fiscal 2005. Our minimum net worth requirement under the Wells Fargo Agreement varies each quarter in relation to our planned operating results. At July 31, 2005, our net worth, as defined, was \$51.7 million compared to the required amount of \$39.0 million. Additionally, payment of common stock dividends is restricted. The net worth and capital expenditures covenants are established annually as of August 1 and were amended on January 25, 2005 to increase the capital expenditures limit and to reduce the required net worth amount to the amounts described above. The Wells Fargo Agreement contains a provision whereby Wells Fargo can call for immediate repayment of all amounts due under the line upon its sole determination that a "material adverse change" has occurred. As a result of this provision, any borrowings under the Wells Fargo Agreement will be classified as short-term debt. There have been no borrowings under the Wells Fargo Agreement.

In December 2002, we entered into an agreement with PharmaBio Development, Inc. ("PharmaBio"), the strategic investment group of Quintiles Transnational Corp., our contract research organization. Under

## ZILA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

this agreement, PharmaBio invested \$500,000 in us. In return for the investment, we agreed to pay PharmaBio an amount equal to 5.0% of all net sales of the OraTest® product in the European Union and the United States. The aggregated amount of the royalty cannot exceed \$1.25 million and the royalty is payable quarterly. The investment was recorded as long-term debt and will be amortized using the effective interest method.

In April 1999, Zila Nutraceuticals, Inc. entered into a transaction with The Industrial Development Authority of the County of Yavapai (the "Authority") in which the Authority issued Industrial Development Revenue Bonds (the "Bonds"). The proceeds from the Bonds were loaned to Zila Nutraceuticals, Inc. for the construction of a new manufacturing and laboratory facility. The initial offerings of Bonds consisted of \$3.9 million Series A and \$104,000 Taxable Series B Bonds and mature in 2019. The Series B Bonds were repaid. The Bonds bear a variable interest rate that was 2.5% at Jul 31, 2005. In connection with the issuance of the Bonds, the Authority required that Zila Nutraceuticals, Inc. maintain, for the benefit of the Bondholders, an irrevocable direct-pay letter of credit to secure payment of principal and interest. Zila, Inc. guarantees the letter of credit. Wells Fargo provides such letter of credit ("Replacement Letter of Credit") in conjunction with the Wells Fargo Agreement. This Replacement Letter of Credit replaced an earlier letter of credit provided by Bank One, which expired in March 2004.

Under the terms of the Replacement Letter of Credit, on February 6, 2004, we placed \$517,000 in an interest bearing collateral account representing the difference between the Replacement Letter of Credit amount and the maximum commitment amount, as defined.

We lease facilities and equipment, some of which are required to be capitalized in accordance with SFAS No. 13, "Accounting for Leases" ("SFAS No. 13"). SFAS No. 13 requires the capitalization of leases meeting certain criteria, with the related asset being recorded in property and equipment and an offsetting amount recorded as a liability.

The note payable for equipment matures in 2006 and bears interest at 13.4%.

Aggregate annual maturities of long-term debt and minimum payments under capital leases for the fiscal years ending July 31 are as follows (in thousands):

	Long-term Debt	Capital Leases	Total Debt
2006 .....	\$ 274	\$ 50	\$ 324
2007 .....	246	51	297
2008 .....	245	43	288
2009 .....	746	12	758
2010 .....	245	—	245
2011 and thereafter .....	1,740	—	1,740
Total .....	3,496	156	3,652
Less current portion .....	274	50	324
Long-term portion .....	\$3,222	\$106	\$3,328

#### 11. Stock Options and Warrants

*Stock Options* — On February 6, 1997, we adopted the Zila, Inc. 1997 Stock Option Award Plan authorizing the Board of Directors to grant options to employees and certain employee directors to purchase up to 1,000,000 shares of common stock. On December 7, 2000, the plan was amended to increase the authorized number of shares to 3,000,000. On October 20, 1989, we adopted the Zila, Inc. Non-Employee Directors Stock Option Plan authorizing the Board of Directors to grant options of 100,000 shares to non-employee members of our Board of Directors for services provided to us as a director. Amendments to the plan

**ZILA, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

dated December 8, 1995 and September 26, 2002 increased the authorized number of shares to 200,000 and 700,000, respectively.

On December 16, 2004, we amended and restated the 1997 Stock Option Award Plan: (i) to change the name of the plan to the 1997 Stock Award Plan; (ii) to consolidate the 1997 Stock Award Plan and the Non-Employee Directors Stock Option plans, including the share reserve; (iii) to increase the number of shares available for grant from 3,700,000 shares to 5,000,000 shares; (iv) to expand the persons eligible to receive awards to allow for the eligibility for grants to all employees, members of our Board of Directors or directors and consultants; (v) to allow us to grant stock-based awards other than stock options; (vi) to revise the plan to provide greater flexibility in the terms of the awards; and (vii) to allow the plan to qualify for the "performance-based" compensation exemption from the limits of Section 162(m) of the Internal Revenue Code of 1986, as amended.

Options granted under the 1997 Stock Award Plan are issuable only to eligible officers, non-employee directors and key employees. The 1997 Stock Award Plan is administered by the Compensation Committee of our board of directors, which determines those individuals who shall receive options, the number of shares of common stock to be granted, and the option price. The options are issuable under the 1997 Stock Award Plan at an exercise price equal to the market closing price on the date of grant. Employee options may be exercised up to ten years from the date of grant, and non-employee directors' options may be exercised up to five years from the date of grant.

Under the 1997 Stock Award Plan and as approved by our Board of Directors on June 23, 2005, our non-employee directors will receive an annual grant of 30,000 shares based on certain tenure and meeting attendance requirements as defined in the plan. New non-employee directors will receive 30,000 shares upon their appointment but are not entitled to receive an annual grant within one year of their initial grant. In addition, our Board of Directors may grant discretionary awards to non-employee directors. These stock options vest quarterly in equal increments.

At July 31, 2005, we also have options for 37,600 shares outstanding at a weighted average exercise price of \$6.26 under a 1988 Stock Option Award Plan. The options were issued at an exercise price no less than the market value at the date of grant and the options may be exercised at any time up to ten years from the date of grant. No shares were available for grant under this plan.

ZILA, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

A summary of the status of the option plans as of July 31, 2005, 2004 and 2003 and changes during the years then ended are presented below (shares in thousands):

	2005		2004		2003	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year . . . .	1,660	\$3.35	1,299	\$2.69	2,196	\$4.42
Granted . . . . .	983	4.11	689	3.93	580	1.59
Exercised . . . . .	(73)	1.76	(207)	2.13	(5)	1.05
Forfeited/expired . . . . .	(225)	4.79	(121)	1.58	(1,472)	4.84
Outstanding at end of year . . . . .	<u>2,345</u>	3.58	<u>1,660</u>	3.36	<u>1,299</u>	2.69
Options exercisable at year-end . . . . .	<u>2,269</u>	3.61	<u>975</u>	3.26	<u>760</u>	3.30
Shares available for future grant . . . . .	<u>2,394</u>					

The following table summarizes information regarding stock options outstanding as of July 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at July 31, 2005	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable at July 31, 2005	Weighted Average Exercise Price
\$0.76-\$2.95 . . . . .	524	5.9	\$1.47	449	\$1.29
\$3.02-\$3.55 . . . . .	566	6.4	3.36	566	3.36
\$3.62-\$4.12 . . . . .	495	9.0	4.07	494	4.07
\$4.20-\$4.65 . . . . .	550	8.0	4.37	550	4.37
\$4.75-\$9.88 . . . . .	<u>210</u>	6.1	6.23	<u>210</u>	6.23
Total . . . . .	<u>2,345</u>	7.2	3.58	<u>2,269</u>	3.61

*Warrants* — We have issued warrants to various investors, shareholders and other third parties in connection with services provided. These warrants were valued using a Black Scholes model and charged to expense. Warrants issued in exchange for goods are expensed at the fair value of the consideration received. During the year ended July 31, 2003 warrants issued for goods or services were valued at \$71,000 and are included as a component of selling, general and administrative expenses.

Activity related to such warrants, which expire at various dates through March 2013, is summarized as follows (shares in thousands):

	Number of Shares	Warrant Price per Share
Outstanding, July 31, 2002 . . . . .	25	\$4.00-5.00
Issued . . . . .	<u>104</u>	0.98-4.00
Outstanding, July 31, 2003 . . . . .	129	0.98-5.00
Issued . . . . .	<u>55</u>	0.74-4.06
Outstanding, July 31, 2004 . . . . .	184	0.74-5.00
Exercised . . . . .	(16)	0.74
Forfeited/expired . . . . .	<u>(35)</u>	4.06-4.91
Outstanding, July 31, 2005 . . . . .	<u>133</u>	0.74-5.00

**ZILA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

*Stock Purchase Plan* — Under the Zila, Inc. Employee Stock Purchase Plan, we are authorized, as of July 31, 2001, to issue up to 2,000,000 shares of common stock to our eligible employees, nearly all of whom are eligible to participate. Eligible employees may have up to 15% of eligible compensation withheld and/or they may make a lump sum payment on the last day of the offering to purchase our common stock. The purchase price for each share of stock is 85% of the lower of the closing price on the first or last day of the offering period. A total of 66,500, 76,800 and 143,700 shares were purchased in fiscal 2005, 2004 and 2003, respectively, for aggregate proceeds of \$190,000, \$213,000 and \$121,000, respectively. Our Employee Stock Purchase Plan is compensatory as defined under SFAS No. 123, and accordingly we recognized noncash stock-based compensation expense of \$33,000, \$37,000, and \$18,000 in fiscal 2005, 2004 and 2003, respectively.

**12. Income Taxes**

The consolidated income tax benefit (provision) consists of the following for the years ended July 31 (in thousands):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Current:			
Federal .....	\$—	\$—	\$ (95)
State .....	<u>(8)</u>	<u>(2)</u>	<u>(93)</u>
Total current .....	<u>(8)</u>	<u>(2)</u>	<u>(188)</u>
Deferred:			
Federal .....	—	—	—
State .....	<u>—</u>	<u>—</u>	<u>—</u>
Total deferred .....	<u>—</u>	<u>—</u>	<u>—</u>
Total consolidated income tax (benefit) provision .....	<u><u>\$(8)</u></u>	<u><u>\$(2)</u></u>	<u><u>\$(188)</u></u>

A reconciliation of the federal statutory rate to the effective income tax rate for the years ended July 31 is as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Federal statutory rate .....	35%	(35)%	35%
Adjustments:			
State income taxes — net of federal tax effects .....	4	—	5
Non-deductible meal and entertainment expenses .....	2	1	1
Non-deductible intangible amortization .....	13	4	4
Increase (decrease) in valuation allowance .....	<u>(53)</u>	<u>30</u>	<u>(43)</u>
Effective tax rate .....	<u><u>1%</u></u>	<u><u>0%</u></u>	<u><u>2%</u></u>

**ZILA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The components of deferred income tax assets and liabilities for the years ended July 31 are shown below (in thousands):

	<u>2005</u>	<u>2004</u>
Deferred income tax assets:		
Net operating loss carry forwards .....	\$ 4,151	\$ 4,078
Book basis versus tax basis differences .....	947	1,416
Alternative minimum tax credit .....	230	230
Miscellaneous reserves and accruals .....	637	797
Other .....	<u>82</u>	<u>77</u>
Total deferred income tax assets .....	<u>6,047</u>	<u>6,598</u>
Deferred income tax liabilities:		
Depreciation and amortization .....	(113)	(174)
Federal income tax on state NOL carryforwards .....	(74)	(73)
Other .....	<u>(254)</u>	<u>(147)</u>
Total deferred income tax liabilities .....	<u>(441)</u>	<u>(394)</u>
Valuation allowance .....	<u>(5,606)</u>	<u>(6,204)</u>
Net deferred income tax assets .....	<u>\$ —</u>	<u>\$ —</u>

Deferred income taxes reflect the tax effect of temporary differences between the amounts of assets and liabilities recognized for financial reporting and tax purposes. We have recorded a valuation allowance for our net deferred tax assets due to a lack of earnings history. We regularly review our past earnings history and trends and projections of future net income to determine whether a valuation allowance is needed. During fiscal years 2005, 2004 and 2003, we determined that it was more likely than not that certain future tax benefits would not be realized. Accordingly, valuation allowances were provided for the entire amount of the net deferred tax assets in these years.

At July 31, 2005, we had federal net operating loss carry forwards of approximately \$11.3 million which expire in years 2009 through 2024.

The other comprehensive losses in fiscal years 2005 (\$9,500), 2004 (\$2,200) and 2003 (\$300) reflect no income tax benefit due to the recording of valuation allowances.

**13. Supplemental Schedule of Cash flow Information**

Supplemental cash flow information for the three fiscal years ended July 31 follows (in thousands):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Interest paid .....	\$168	\$158	\$197
Income taxes paid .....	14	193	—
Capital lease obligation for new equipment .....	6	232	—
Noncash effect of removal of contractual restrictions on issued common stock .....	49	135	—
Liability satisfied through issuance of warrants .....	—	28	—



## ZILA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 14. Convertible Preferred Stock

On February 1, 2001, we issued 100,000 shares of Series B Convertible Preferred Stock to National Healthcare Manufacturing Corporation, as part of the acquisition of IST. The preferred stock is convertible into shares of common stock at any time at a conversion ratio of one to one. The holders of the preferred stock are entitled to receive cumulative quarterly dividends at a rate of \$0.0975 per share per fiscal quarter, payable in arrears. Holders of the preferred shares have no voting rights except as required by applicable law. We paid dividends of \$68,250, \$19,500 and \$49,000 during fiscal years 2005, 2004 and 2003, respectively. At July 31, 2005, accumulated accrued dividends are \$9,750.

#### 15. Treasury Stock

During the quarter ended January 31, 2000, we began acquiring shares of our common stock under our stock repurchase program announced in November 1999. The program authorized the repurchase of up to one million shares of Zila common stock from time to time on the open market depending on market conditions and other factors. As of July 31, 2005, we had purchased 225,100 shares of common stock at an aggregate cost of \$571,000. We have made no purchases of our common stock under this program since fiscal 2003, and have suspended purchases under the program. In fiscal 2005, we reissued 6,689 shares of treasury stock for a stock award granted to our Chief Executive Officer.

#### 16. Leases

We lease offices, warehouse facilities and certain equipment, under capital and operating leases, with terms generally ranging up to 2010 with options to renew for additional periods.

We entered into new capital leases totaling \$6,000 and \$232,000 during fiscal 2005 and 2004, respectively. These capital leases are non-cash transactions and, accordingly, have been excluded from the Statements of Consolidated Cash Flows. Interest paid as part of capital lease obligations was approximately \$9,000 and \$15,000 in fiscal 2005 and 2004, respectively. Amortization of assets recorded under capital leases was included in depreciation expense.

Operating leases are charged to expense as incurred. Rent expense for fiscal years 2005, 2004 and 2003 totaled \$369,000, \$321,000 and \$469,000, respectively.

As part of our strategy to employ financial assets in core business competencies, on January 30, 2004, we completed the sale and a five-year leaseback of our corporate headquarters for approximately \$1.7 million in net cash. We realized a gain of \$1.2 million, of which we recognized approximately \$470,000 in the quarter ended January 31, 2004. The \$470,000 gain represents the excess of the net proceeds over the net present value of the future lease payments. The balance of the gain of \$765,000 was deferred and amortized on a straight-line basis over the five-year lease term as a reduction of rent expense in general and administrative expenses. The leaseback is accounted for as an operating lease under SFAS 13.

**ZILA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

Future minimum lease payments as of July 31, 2005 for capital and operating leases follow (in thousands):

	<u>Capital Leases</u>	<u>Operating Leases</u>	<u>Total</u>
2006 .....	\$ 54	\$ 476	\$ 530
2007 .....	52	484	536
2008 .....	46	403	449
2009 .....	12	285	297
2010 .....	1	203	204
Thereafter .....	<u>—</u>	<u>69</u>	<u>69</u>
Total minimum lease payments .....	\$165	<u>\$1,920</u>	<u>\$2,085</u>
Less: amounts representing interest .....	<u>9</u>		
Present value of minimum lease payments .....	156		
Less: Current portion of capital lease obligations .....	<u>50</u>		
Long-term portion of capital lease obligations .....	<u>\$106</u>		

**17. Commitments and Contingencies**

*FDA approval of the OraTest® product*

We are pursuing FDA approval of a New Drug Application (“NDA”) for our OraTest® product. Factors that will affect the cost and timing of completion of the clinical trials include, but are not limited to: (i) patient enrollment rates; (ii) cancer and pre-cancer rates within the study population; (iii) compliance with the study protocol and related monitoring; (iv) level of funding throughout the study; and (v) FDA acceptance of our program modifications.

At July 31, 2005, we had approximately \$482,000 of OraTest® rinse and swab inventory and ZTC™ drug substance, the active ingredient in the OraTest® product, and its related components. We intend to realize the value of this inventory and drug substance through its consumption during the conduct of the clinical trials, process development, toxicology studies and validation testing of our manufacturing process. The drug substance currently has shelf lives with varying expiration dates. Our periodic testing has indicated that the drug substance is stable and we anticipate being able to extend the expiration dates of the entire drug substance beyond their current expiration dates if our plans are delayed. However, no assurance can be given in this regard.

*ViziLite®*

We had \$290,000 of ViziLite® product in inventory and approximately \$1.8 million of associated net long-lived assets as of July 31, 2005. In fiscal 2004, we adjusted our product-to-market strategy for ViziLite® based on our experiences in promoting awareness, education, trial and repeat purchases of this unique product within the dental profession. The redirected product rollout strategy is currently in the implementation stage and thus the acceptance of ViziLite® cannot be determined at this time. If sales do not ultimately reach certain minimum levels, we may have to reduce the carrying value of the assets related to ViziLite®.

*Litigation*

Except as described below, we are not a party to any pending legal proceedings other than claims that arise in the conduct of our business. While we currently believe that the ultimate outcome of these

## ZILA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

proceedings will not have a material adverse effect on our consolidated financial condition or results of operations, litigation is subject to inherent uncertainties. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on our net income in the period in which a ruling occurs. Our estimate of the potential impact of the following legal proceedings on our financial position and our results of operation could change in the future.

In connection with the acquisition of patent rights in 1980, we agreed to pay to Dr. James E. Tinnell (“Tinnell”), the inventor of one of our former treatment compositions, a royalty of 5% of gross sales of the invention disclosed in his then pending patent application. In September 2000, we notified Tinnell that we would no longer pay such royalties because the obligations ceased in August 1998 when the related product patents expired and we requested reimbursement of royalties paid since August 1998. We then filed suit in the Federal District Court requesting a declaratory judgment that we had no royalty obligations to Tinnell and requested judgment for the overpaid royalties. On April 22, 2004, the Court, in part, ruled in our favor, stating that our royalty obligations to Tinnell ceased in August 1998, however, our request for reimbursement of overpaid royalties was dismissed. Tinnell filed a notice of appeal and we have filed a notice of cross-appeal. Briefs have been filed by both parties with the Ninth Circuit Court of Appeals.

In early December 2004, we became aware of a purported class action lawsuit filed in the Superior Court of the State of Arizona for Maricopa County against Matrixx Initiatives, Inc. and a number of other defendants, including us and IST. The lawsuit alleges that the Zicam Cold Remedy Product manufactured by Matrixx Initiatives, Inc., a former customer of IST, caused damage to the sense of smell and/or taste of the plaintiffs. Other defendants in the lawsuit include manufacturers and retailers. IST had produced swabs and containers for the Zicam Cold Remedy Product for a limited period that ended in March 2004. We and IST have not yet been served with this lawsuit; however, if we and IST are made parties to the lawsuit, we will contest it vigorously. We believe that the plaintiffs’ claims with respect to us and IST are without merit.

On January 25, 2005, Ronald Fugate, a former employee, filed a lawsuit in the Superior Court of the State of Arizona alleging wrongful termination in the case captioned Ronald Fugate v. Zila, Inc., et al CV2005-001218. A confidential mediated settlement was reached in July 2005.

#### *Employment Agreements*

We have employment agreements with certain officers and key employees which provide for eligibility for future stock awards and for separation benefits, in certain situations. In addition, the employment agreement with our Chief Executive Officer provides for salary, incentive bonus, and separation benefits.

#### *Daleco Agreement*

On June 22, 1992, we entered into an agreement with Daleco Zila Partners II, L.P. and Daleco Capital Corporation (collectively “Daleco”) to market and promote certain new Zila products (“New Products”). We engaged Daleco to conduct a comprehensive marketing and promotion effort with respect to the New Products. At July 31, 2005, Daleco had spent approximately \$1,820,000 pursuant to its marketing and promotion obligations. Under the Agreement Daleco received commissions on gross sales that resulted from their efforts. Daleco has ceased its marketing and promotion effort and has been paid all commissions that are due under the Agreement as it relates to those efforts.

#### *Vital Health Sciences Ltd. License Agreement*

On October 31, 2003, we entered into a license agreement with Vital Health Sciences, Ltd. (“Vital Health”) that grants us the exclusive rights in the human dietary supplement market in the United States, Canada and Indonesia for certain issued and pending patents, know-how and data pertaining to tocopheryl phosphates. A subsequent agreement entered into on August 4, 2004, extends the terms of the original

## ZILA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

agreement to give us extensive rights in the animal dietary supplement market in these countries. We also have a right of first refusal for all other international human dietary supplement markets under the agreement. Zila Nutraceuticals uses the patented tocopheryl phosphate technology to produce its Ester-E® product tailored for the dietary supplement market. Under the agreement, starting in fiscal 2005 we are required to make royalty payments based on certain levels of sales volume. Additionally, we are subject to minimum annual royalty payment amounts, as defined. The initial term of the license is five years, and we have the right, unilaterally, to extend the term until the expiration of the last of the issued patents covered by the license agreement. Eight patents have been issued in Australia, The United States and/or South Africa, while other applications are pending.

#### *Supply Arrangements*

Our wholly-owned subsidiary, Zila Nutraceuticals, Inc., entered into three-year supply agreements with two major suppliers for the purchase of \$26.7 million of ascorbic acid of which \$21.0 million remains to be purchased in future periods. Ascorbic acid is the primary ingredient in our Ester-C® products. Purchases under one of these agreements commenced in July 2004 and with the other starting in January 2005. The agreements provide a substantial portion of our anticipated annual requirements for ascorbic acid and will provide important cost predictability during the terms of the agreements. Should prices fall sharply, we would be at risk of being committed to purchase ascorbic acid at higher than market prices. If our sales should decline significantly, we could be obligated to purchase supplies in excess of our needs.

#### *Indemnifications*

During the normal course of business, we make certain indemnities, commitments and guarantees under which we may be required to make payments in relation to certain transactions. These include: (i) intellectual property indemnities to customers in connection with the use, sales and/or license of products and services; (ii) indemnities to customers in connection with losses incurred while performing services on their premises; (iii) indemnities to vendors and service providers pertaining to claims based on negligence or willful misconduct; and (iv) indemnities involving the representations and warranties in certain contracts. In addition, under our by-laws we are committed to our directors and officers for providing for payments upon the occurrence of certain prescribed events. The majority of these indemnities, commitments and guarantees do not provide for any limitation on the maximum potential for future payments that we could be obligated to make. To help address these risks, we maintain general business liability insurance coverage, including product, commercial, general, fiduciary, employment practices and directors' and officers' liability coverages. We have not recorded a liability for these indemnities, commitments and other guarantees in the Consolidated Balance Sheets.

#### **18. Related Party Transactions**

In fiscal 2004, we paid \$6,086 to Hogan and Hartson, a law firm in which a member of our Board of Directors, Mr. John Porter, is a partner. The payment was related to consulting work performed by this firm.

#### **19. Employee Benefit Plan**

We make available to all eligible employees, the Zila, Inc. 401(k) Savings and Retirement Plan (the "Zila Plan"). We may make matching or profit sharing contributions to the Zila Plan. Our contributions to the Zila Plan were \$185,000, \$223,000 and \$191,000 in fiscal 2005, 2004 and 2003, respectively.

**ZILA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**20. Accrued Liabilities**

Accrued liabilities consist of the following at July 31 (in thousands):

	<u>2005</u>	<u>2004</u>
Accrued professional and consulting fees .....	\$1,248	\$ 964
Accrued royalties .....	815	4
Accrued employee compensation and related taxes .....	712	776
Other .....	943	877
Total accrued liabilities .....	<u>\$3,718</u>	<u>\$2,621</u>

**21. Segment Information**

Our business is organized into three major groups, all of which have distinct product lines, brand names and are managed as autonomous business units. The following reporting segments have been identified for purposes of applying SFAS No. 131 "Disclosures about Segments of an Enterprise and Related Information": The Nutraceuticals Business Unit, which includes Zila Nutraceuticals, Inc., the manufacturer and marketer of *Advanced Protection* Ester-C® and Ester-E®, proprietary, branded, highly effective forms of vitamins C and E; The Pharmaceuticals Business Unit which includes Zila Pharmaceuticals, Inc. and the ViziLite® chemiluminescent light for the illumination of oral mucosal abnormalities, Peridex® prescription periodontal rinse, and the plastic molded products of IST; and The Zila Biotechnology Business Unit, which includes Zila Biotechnology Inc., Zila Technical, Inc., and Zila Limited, and is the research, development and licensing business specializing in pre-cancer/cancer detection through its patented Zila® Tolonium Chloride and OraTest® technologies and now manages the OraTest® product, an oral cancer diagnostic system.

We evaluate performance and allocate resources to segments based on operating results. In fiscal 2003, we allocated the net gain of approximately \$14.8 million derived from the settlement with our former contract research organization based principally upon the relative contributions of personnel from Corporate and the Biotechnology segment in helping to achieve such settlement.

**ZILA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

Information about our reported segments (with corporate representing a reconciling item) is set forth below for each of the three fiscal years ended July 31 (in thousands):

	<u>Nutraceuticals</u>	<u>Pharmaceuticals</u>	<u>Biotechnology</u>	<u>Corporate</u>	<u>Total</u>
Net revenues from continuing operations:					
2005.....	\$38,471	\$ 5,846	\$ 8	\$ —	\$44,325
2004.....	32,432	8,971	2	—	41,405
2003.....	29,423	9,767	20	—	39,210
Income (loss) from continuing operations before income taxes and accounting change:					
2005.....	9,022	(2,614)	(8,694)	(6,736)	(9,022)
2004.....	8,300	(765)	(7,195)	(4,712)	(4,372)
2003.....	7,733	406	3,474	186	11,799
Identifiable assets from continuing operations:					
2005.....	34,083	10,867	19,076	1,392	65,418
2004.....	31,469	11,499	15,583	3,558	62,109
2003.....	29,290	14,520	7,983	17,227	69,020
Capital expenditures:					
2005.....	735	279	737	120	1,871
2004.....	759	31	37	450	1,277
2003.....	175	153	509	95	932
Depreciation and amortization:					
2005.....	1,130	619	732	207	2,688
2004.....	1,057	644	683	99	2,483
2003.....	986	525	715	120	2,346

Revenues from customers attributed to all foreign countries were \$6,650,000, \$5,416,000 and \$8,948,000 in fiscal years 2005, 2004 and 2003, respectively.

**ZILA, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**22. Quarterly Financial Data (Unaudited)**

Quarterly financial information is presented in the following summary (in thousands, except per share amounts):

	2005			
	Quarter Ended			
	October 31	January 31	April 30	July 31
Net revenues .....	\$ 9,876	\$10,931	\$12,020	\$11,498
Gross profit .....	6,406	7,251	8,110	7,173
Loss from continuing operations .....	(3,203)	(2,744)	(2,229)	(854)
Income from discontinued operations .....	491	88	78	9,472
Net income (loss) .....	\$(2,712)	\$(2,656)	\$(2,151)	\$ 8,618
Basic and diluted net income (loss) per share:				
Loss from continuing operations .....	\$ (0.07)	\$ (0.06)	\$ (0.05)	\$ (0.02)
Income (loss) from discontinued operations .....	0.01	0.00	0.00	0.21
Net loss .....	<u>\$ (0.06)</u>	<u>\$ (0.06)</u>	<u>\$ (0.05)</u>	<u>\$ 0.19</u>

	2004			
	Quarter Ended			
	October 31	January 31	April 30	July 31
Net revenues .....	\$ 9,811	\$11,533	\$10,802	\$9,259
Gross profit .....	5,796	6,753	6,794	5,942
Loss from continuing operations .....	(1,830)	(795)	(1,747)	(3)
Income (loss) from discontinued operations .....	262	(167)	180	(237)
Net loss .....	\$(1,568)	\$ (962)	\$(1,567)	\$ (240)
Basic and diluted net income (loss) per share:				
Loss from continuing operations .....	\$ (0.05)	\$ (0.02)	\$ (0.03)	\$ 0.00
Income (loss) from discontinued operations .....	0.01	0.00	0.00	(0.01)
Net loss .....	<u>\$ (0.04)</u>	<u>\$ (0.02)</u>	<u>\$ (0.03)</u>	<u>\$(0.01)</u>

**SCHEDULE II**  
**VALUATION AND QUALIFYING ACCOUNTS**

<u>Description</u>	<u>Balance at Beginning of Period</u>	<u>Charged to Costs and Expenses</u>	<u>Deductions</u>	<u>Balance at End of of Period</u>
		(In thousands)		
Allowance for doubtful accounts receivable:				
July 31, 2003 .....	\$ 133	\$458	\$ 274	\$ 317
July 31, 2004 .....	317	(90)	168	59
July 31, 2005 .....	59	37	54	42
Allowance for sales returns:				
July 31, 2003 .....	185	201	92	294
July 31, 2004 .....	294	154	235	213
July 31, 2005 .....	213	11	116	108
Inventory reserve:				
July 31, 2003 .....	293	363	301	355
July 31, 2004 .....	355	172	330	197
July 31, 2005 .....	197	290	347	140
Deferred tax valuation allowance:				
July 31, 2003 .....	9,102	—	3,843	5,259
July 31, 2004 .....	5,259	945	—	6,204
July 31, 2005 .....	6,204	—	598	5,606

The table above includes all consolidated valuation and qualifying accounts, including those in "assets held for sale" for IST. The valuation and qualifying accounts for IST reported as "assets held for sale" at July 31 are:

	<u>July 31</u>	
	<u>2004</u>	<u>2003</u>
Allowance for doubtful accounts receivable .....	\$—	\$17
Allowance for sales returns .....	—	50



**Certification of the Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Douglas D. Burkett, certify that:

1. I have reviewed this annual report on Form 10-K of Zila, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 3a-15(f) and 15d-15(f)) 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. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. 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
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ DOUGLAS D. BURKETT, PH. D.

Douglas D. Burkett, Ph. D.  
Chairman of the Board, President and  
Chief Executive Officer  
(Principal Executive Officer)

Date: October 12, 2005

**Certification of the Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Andrew A. Stevens, certify that:

1. I have reviewed this annual report on Form 10-K of Zila, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 3a-15(f) and 15d-15(f)) 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. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements of for external purposes in accordance with generally accepted accounting principles;
  - c. 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
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ ANDREW A. STEVENS

Andrew A. Stevens  
Vice President and Chief Financial Officer  
(Principal Financial Officer)

Date: October 12, 2005

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

This certification is not deemed filed pursuant to the Securities Exchange Act of 1934, as amended, and does not constitute a part of the Annual Report of Zila, Inc. (the "Company") on Form 10-K for the period ended July 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report").

In connection with the Report of the Company, I, Douglas D. Burkett, President and Chief Executive Officer of the Company, hereby certify pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge that:

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

/s/ DOUGLAS D. BURKETT, PH.D.

Douglas D. Burkett, Ph.D.  
Chairman of the Board, President  
and Chief Executive Officer  
*(Principal Executive Officer)*

Date: October 12, 2005

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

This certification is not deemed filed pursuant to the Securities Exchange Act of 1934, as amended, and does not constitute a part of the Annual Report of Zila, Inc. (the "Company") on Form 10-K for the period ended July 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report").

In connection with the Report of the Company, I, Andrew A. Stevens, Vice President and Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ ANDREW A. STEVENS

Andrew A. Stevens  
Vice President and Chief Financial Officer  
*(Principal Financial Officer)*

Date: October 12, 2005