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PROVECTUS PHARMACEUTICALS INC
Form 10KSB
March 31, 2005

United States Securities And Exchange Commission
Washington, DC 20549

FORM 10-KSB

(Mark One)

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2004; 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: 0-9410

Provectus Pharmaceuticals, Inc.
(Name of Small Business Issuer in Its Charter)

Nevada

90-0031917

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
Identification Number)

7327 Oak Ridge Highway, Suite A, Knoxville, Tennessee

37931

(Address of Principal Executive Offices)

(Zip Code)

865/769-4011

(Issuer's Telephone Number, Including Area Code)

Securities registered under Section 12(b) of the Exchange Act:
None

(Title of Class)

Securities registered under Section 12(g) of the Exchange Act:
Common shares, par value \$.001 per share

(Title of Class)

Check whether the issuer: (1) 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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB.

The issuer's revenues for the most recent fiscal year were \$21,072. The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of March 17, 2005, was \$15,947,003 (computed

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on the basis of \$0.97 per share).

The number of shares outstanding of the issuer's stock, \$0.001 par value per share, as of March 17, 2005 was 16,440,209.

Documents incorporated by reference in Part III hereof: Proxy Statement for 2005 Annual Meeting of Stockholders

Transitional Small Business Disclosure Format (check one): Yes No

Provectus Pharmaceuticals, Inc. Annual Report on Form 10-KSB

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PART I

Item 1. Description of Business.

History

Provectus Pharmaceuticals, Inc., formerly known as "Provectus

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Pharmaceutical, Inc." and "SPM Group, Inc.," was incorporated under Colorado law on May 1, 1978. SPM Group ceased operations in 1991, and became a development-stage company effective January 1, 1992, with the new corporate purpose of seeking out acquisitions of properties, businesses, or merger candidates, without limitation as to the nature of the business operations or geographic location of the acquisition candidate.

On April 1, 2002, SPM Group changed its name to "Provectus Pharmaceutical, Inc." and reincorporated in Nevada in preparation for a transaction with Provectus Pharmaceuticals, Inc., a privately-held Tennessee corporation, which we refer to as "PPI." On April 23, 2002, an Agreement and Plan of Reorganization between Provectus Pharmaceutical and PPI was approved by the written consent of a majority of the outstanding shares of Provectus Pharmaceutical. As a result, holders of 6,680,000 shares of common stock of Provectus Pharmaceutical exchanged their shares for all of the issued and outstanding shares of PPI. As part of the acquisition, Provectus Pharmaceutical changed its name to "Provectus Pharmaceuticals, Inc." and PPI became a wholly owned subsidiary of Provectus. For accounting purposes, we treat this transaction as a recapitalization of PPI.

On November 19, 2002, we acquired Valley Pharmaceuticals, Inc., a privately-held Tennessee corporation formerly known as Photogen, Inc., by merging our subsidiary PPI with and into Valley and naming the surviving corporation "Xantech Pharmaceuticals, Inc." Valley had minimal operations and had no revenues prior to the transaction with the Company. By acquiring Valley, we acquired our most important intellectual property, including issued U.S. patents and patentable inventions, with which we intend to develop:

- o prescription drugs, medical and other devices (including laser devices) and over-the-counter pharmaceutical products in the fields of dermatology and oncology; and
- o technologies for the preparation of human and animal vaccines, diagnosis of infectious diseases and enhanced production of genetically engineered drugs.

Prior to the acquisition of Valley, we were considered to be, and continue to be, in the development stage and had not generated any revenues from the assets we acquired.

On December 5, 2002, we acquired the assets of Pure-ific L.L.C., a Utah limited liability company, and created a wholly owned subsidiary, Pure-ific Corporation, to operate that business. We acquired the product formulations for Pure-ific personal sanitizing sprays, along with the "Pure-ific" trademarks. We intend to continue product development and begin to market a line of personal sanitizing sprays and related products to be sold over the counter under the "Pure-ific" brand name.

Description Of Business

Overview

Provectus, and its five wholly owned subsidiaries:

- o Xantech Pharmaceuticals, Inc.
- o Pure-ific Corporation
- o Provectus Biotech, Inc.
- o Provectus Devicetech, Inc.
- o Provectus Pharmatech, Inc.

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(which we refer to as our subsidiaries) develop, license and market and plan to sell products in three sectors of the healthcare industry:

- o Over-the-counter products, which we refer to in this report as "OTC products;"

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- o Prescription drugs; and
- o Medical device systems

We manage Provectus and our subsidiaries on an integrated basis and when we refer to "we" or "us" or "the Company" in this Annual Report on Form 10-KSB, we refer to all six corporations considered as a single unit. Our principal executive offices are located at 7327 Oak Ridge Highway, Suite A, Knoxville, Tennessee 37931, telephone 865/769-4011.

Through discovery and use of state-of-the-art scientific and medical technologies, the founders of our pharmaceutical business have developed a portfolio of patented, patentable, and proprietary technologies that support multiple products in the prescription drug, medical device and OTC products categories (including patented technologies for: (a) treatment of cancer; (b) novel therapeutic medical devices; (c) enhancing contrast in medical imaging; (d) improving signal processing during biomedical imaging; and (e) enhancing production of biotechnology products). Our prescription drug products encompass the areas of dermatology and oncology and involve several types of small molecule-based drugs. Our medical device systems include therapeutic and cosmetic lasers, while our OTC products address markets primarily involving skincare applications. Because our prescription drug candidates and medical device systems are in the early stages of development, they are not yet on the market and there is no assurance that they will advance to the point of commercialization.

Our first commercially available products are directed into the OTC market, as these products pose minimal or no regulatory compliance barriers to market introduction. For example, the active pharmaceutical ingredient (API) in our ethical products is already approved for other medical uses by the FDA and has a long history of safety for use in humans. This use of known APIs for novel uses and in novel formulations minimizes potential adverse concerns from the FDA, since considerable safety data on the API is available (either in the public domain or via license or other agreements with third parties holding such information). In similar fashion, our OTC products are based on established APIs and, when possible, utilize formulations (such as aerosol or cream formulations) that have an established precedent. (For more information on compliance issues, see "Federal Regulation of Therapeutic Products" below.) In this fashion, we believe that we can diminish the risk of regulatory bars to the introduction of safe, consumer-friendly products and minimize the time required to begin generating revenues from product sales. At the same time, we continue to develop higher-margin prescription pharmaceuticals and medical devices, which have longer development and regulatory approval cycles.

Over-the-Counter Pharmaceuticals

Our OTC products are designed to be safer and more specific than competing products. Our technologies offer practical solutions for a number of intractable maladies, using ingredients that have limited or no side effects compared with existing products. To develop our OTC products, we typically use compounds with potent antibacterial and antifungal activity as building blocks and combine these building blocks with anti-inflammatory and moisture-absorbing agents. Products with these properties can be used for treatment of a large number of

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skin afflictions, including:

- o hand irritation associated with use of disposable gloves
- o eczema
- o mild to moderate acne

Where appropriate, we have filed or will file patent applications and will seek other intellectual property protection to protect our unique formulations for relevant applications.

GloveAid

Personnel in many occupations and industries now use disposable gloves daily in the performance of their jobs, including:

- o Airport security personnel;
- o Food handling and preparation personnel;

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- o Sanitation workers;
- o Postal and package delivery handlers and sorters;
- o Laboratory researchers;
- o Health care workers such as hospital and blood bank personnel; and
- o Police, fire and emergency response personnel.

Accompanying the increased use of disposable gloves is a mounting incidence of chronic skin irritation. To address this market, we have developed GloveAid, a hand cream with both antiperspirant and antibacterial properties, to increase the comfort of users' hands during and after the wearing of disposable gloves. During 2003, we ran a pilot scale run at the manufacturer of GloveAid.

The chronic skin irritation that accompanies the long-term use of disposable gloves has been characterized as an allergic-like reaction to the glove materials. Currently, physicians treat the condition using steroids and other immunosuppressive therapies. To avoid possible regulatory bars, we are marketing GloveAid as a means to increase users' comfort, not as a long-term therapy for treatment of chronic skin irritation. However, as we obtain data regarding people who have existing chronic skin irritation, we may seek regulatory approval of GloveAid to permit us to market it as a therapy for chronic skin problems associated with wearing of disposable gloves. If we decide to obtain this regulatory approval, we anticipate that our projected sales of GloveAid would increase significantly. Obtaining this approval would require the completion of glove viability tests required by the United States Food and Drug Administration, which we refer to as the "FDA," and responding to the FDA's comments relating to these tests. We estimate regulatory approval would cost approximately \$300,000 and would take from two to three years to obtain.

Pure-ific

Our Pure-ific line of products includes two quick-drying sprays, Pure-ific and Pure-ific Kids, that immediately kill up to 99.9% of germs on skin and prevent regrowth for 6 hours. We have determined the effectiveness of Pure-ific based on our internal testing and testing performed by Paratus Laboratories H.B., an independent research lab. Pure-ific products help prevent the spread of germs and thus complement our other OTC products designed to treat irritated skin or skin conditions such as acne, eczema, dandruff and fungal infections. Our Pure-ific sprays have been designed with convenience in mind and are targeted towards mothers, travelers, and anyone concerned about the spread of sickness-causing germs. During 2003 and 2004, we identified and engaged sales and brokerage forces for Pure-ific. We emphasized getting sales in independent

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pharmacies and mass (chain store) markets. The supply chain for Pure-ific was established with the ability to support large-scale sales and a starting inventory was manufactured and stored in a contract warehouse/fulfillment center. In addition, a website for Pure-ific was developed with the ability for supporting on-line sales of the antibacterial hand spray. We intend to continue developing our distribution network for these products and expect to expand the Pure-ific product line to include additional applications.

Dermatology

A number of dermatological conditions, including psoriasis, eczema, and acne, result from a superficial infection which triggers an overwhelming immune response. We anticipate developing OTC products similar to the GloveAid line for the treatment of mild to moderate cases of psoriasis, eczema, and acne. Wherever possible, we intend to formulate these products to minimize or avoid significant regulatory bars that might adversely impact time to market.

Prescription Drugs

We are developing a number of prescription drugs which we expect will provide minimally invasive treatment of chronic severe skin afflictions such as psoriasis, eczema, and acne; and several life-threatening cancers such as those of the liver, breast and prostate. We believe that our products will be safer and more specific than currently existing products. Use of topical or other direct delivery formulations allows these potent products to be conveniently and effectively delivered only to diseased tissues, thereby enhancing both safety and effectiveness. The ease of use and superior performance of these products may eventually lead to extension into OTC applications currently serviced by

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less safe, more expensive alternatives. All of these products are in the pre-clinical or clinical trial stage.

Dermatology

Our most advanced prescription drug candidate for treatment of topical diseases on the skin is Xantryl, a topical gel. PV-10, the active ingredient in Xantryl, is "photoactive": it reacts to light of certain wavelengths, increasing its therapeutic effects. PV-10 also concentrates in diseased or damaged tissue but quickly dissipates from healthy tissue. By developing a "photodynamic" treatment regimen (one which combines a photoactive substance with activation by a source emitting a particular wavelength of light) around these two properties of PV-10, we can deliver a higher therapeutic effect at lower dosages of active ingredient, thus minimizing potential side effects including damage to nearby healthy tissues. PV-10 is especially responsive to green light, which is strongly absorbed by the skin and thus only penetrates the body to a depth of about three to five millimeters. For this reason, we have developed Xantryl combined with green-light activation for topical use in surface applications where serious damage could result if medicinal effects were to occur in deeper tissues.

Acute psoriasis. Psoriasis is a common chronic disorder of the skin characterized by dry scaling patches, called "plaques," for which current treatments are few and those that are available have potentially serious side effects. According to Roenigk and Maibach (Psoriasis, Third Edition, 1998), there are approximately five million people in the United States who suffer from psoriasis, with an estimated 160,000 to 250,000 new psoriasis cases each year. There is no known cure for the disease at this time. According to the National Psoriasis Foundation, the majority of psoriasis sufferers, those with mild to moderate cases, are treated with topical steroids that can have unpleasant side

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effects; none of the other treatments for moderate cases of psoriasis have proven completely effective. The 25-30% of psoriasis patients who suffer from more severe cases generally are treated with more intensive drug therapies or PUVA, a light-based therapy that combines the drug Psoralen with exposure to ultraviolet A light. While PUVA is one of the more effective treatments, it increases a patient's risk of skin cancer.

We believe that Xantryl activated with green light offers a superior treatment for acute psoriasis because it selectively treats diseased tissue with negligible potential for side effects in healthy tissue; moreover, the therapy has shown promise in comprehensive Phase 1 clinical trials. The objective of a Phase 1 clinical trial is to determine if there are safety concerns with the therapy. In these studies, involving more than 50 test subjects, Xantryl was applied topically to psoriatic plaques and then illuminated with green light. In our first study, a single-dose treatment yielded an average reduction in plaque thickness of 59% after 30 days, with further response noted at the final follow-up examination 90 days later. Further, no pain, significant side effects, or evidence of "rebound" (increased severity of a psoriatic plaque after the initial reduction in thickness) were observed in any treated areas. This degree of positive therapeutic response is comparable to that achieved with potent steroids and other anti-inflammatory agents, but without the serious side effects associated with such agents. We are continuing the required Food and Drug Administration reporting to support the active Investigational New Drug application for Xantryl's Phase 2 clinical trials on psoriasis. The required reporting includes the publication of results regarding the multiple treatment scenario of the active ingredient in Xantryl. We expect to conduct Phase 2 studies in the near future, in which we expect to assess the potential for remission of the disease using a regimen of weekly treatments similar to those used for PUVA.

Actinic Keratosis. According to Schwartz and Stoll (Fitzpatrick's Dermatology in General Medicine, 1999), actinic keratosis, or "AK" (also called solar keratosis or senile keratosis), is the most common pre-cancerous skin lesion among fair-skinned people and is estimated to occur in over 50% of elderly fair-skinned persons living in sunny climates. These experts note that nearly half of the approximately five million cases of skin cancer in the U.S. may have begun as AK. The standard treatments for AK (primarily comprising excision, cryotherapy, and ablation with topical 5-fluorouracil) are often painful and frequently yield unacceptable cosmetic outcomes due to scarring. Building on our experience with psoriasis, we are assessing use of Xantryl with

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green-light activation as a possible improvement in treatment of early and more advanced stages of AK. We completed an initial Phase 1 clinical trial of the therapy for this indication in 2001 with the predecessor company that was acquired in 2002. This study, involving 24 subjects, examined the safety profile of a single treatment using topical Xantryl with green light photoactivation; no significant safety concerns were identified. We are assessing the data from the study as a possible basis for further clinical development of Xantryl for AK.

Severe Acne. According to Berson et al. (Cutis. 72 (2003) 5-13), acne vulgaris affects approximately 17 million individuals in the U.S., causing pain, disfigurement, and social isolation. Moderate to severe forms of the disease have proven responsive to several photodynamic regimens, and we anticipate that Xantryl can be used as an advanced treatment for this disease. Pre-clinical studies show that the active ingredient in Xantryl readily kills bacteria associated with acne. This finding, coupled with our clinical experience in psoriasis and actinic keratosis, suggests that therapy with Xantryl will exhibit no significant side effects and will afford improved performance relative to other therapeutic alternatives. If correct, this would be a major advance over

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currently available products for severe acne.

As noted above, we are researching multiple uses for Xantryl with green-light activation. Multiple-indication use by a common pool of physicians - dermatologists, in this case - should reduce market resistance to this new therapy.

Oncology

Oncology is another major market where our planned products may afford competitive advantage compared to currently available options. We are developing Provecta, a sterile injectible form of PV-10, for direct injection into tumors. Because PV-10 is retained in diseased or damaged tissue but quickly dissipates from healthy tissue, we believe we can develop therapies that confine treatment to cancerous tissue and reduce collateral impact on healthy tissue. During 2003 and 2004, we have been working toward completion of the extensive scientific and medical materials necessary for filing an Investigational New Drug (IND) application for Provecta in anticipation of beginning Phase 1 clinical trials for breast and liver cancer. This IND was filed and cleared by the RDA in 2004 and sets the stage for Phase 1 clinical trials.

Liver Cancer. The current standard of care for liver cancer is ablative therapy (which seeks to reduce a tumor by poisoning, freezing, heating, or irradiating it) using either a localized injection of ethanol (alcohol), cryosurgery, radiofrequency ablation, or ionizing radiation such as X-rays. Where effective, these therapies have many side effects; selecting therapies with fewer side effects tends to reduce overall effectiveness. Combined, ablative therapies have a five-year survival rate of 33% - meaning that only 33% of those liver cancer patients whose cancers are treated using these therapies survive for five years after their initial diagnoses. In pre-clinical studies we have found that direct injection of Provecta into liver tumors quickly ablates treated tumors, and can trigger an anti-tumor immune response leading to eradication of residual tumor tissue and distant tumors. Because of the natural regenerative properties of the liver and the highly localized nature of the treatment, this approach appears to produce no significant side effects. Based on these encouraging preclinical results, we are assessing strategies for initiation of clinical trials of Provecta for treatment of liver cancer.

Breast Cancer. Breast cancer afflicts over 200,000 U.S. citizens annually, leading to over 40,000 deaths. Surgical resection, chemotherapy, radiation therapy, and immunotherapy comprise the standard treatments for the majority of cases, resulting in serious side effects that in many cases are permanent. Moreover, current treatments are relatively ineffective against metastases, which in many cases are the eventual cause of patient mortality. Pre-clinical studies using human breast tumors implanted in mice have shown that direct injection of Provecta into these tumors ablates the tumors, and, as in the case of liver tumors, may elicit an anti-tumor immune response that eradicates distant metastases. Since fine-needle biopsy is a routine procedure for diagnosis of breast cancer, and since the needle used to conduct the biopsy also could be used to direct an injection of Provecta into the tumor, localized destruction of suspected tumors through direct injection of Provecta clearly has the potential of becoming a primary treatment. We are evaluating options for initiating clinical studies of direct injection of Provecta into breast tumors, and expect to formulate final plans based on results from clinical studies of

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our indication for Provecta in liver cancer.

Prostate Cancer. Cancer of the prostate afflicts approximately 190,000 U.S. men annually, leading to over 30,000 deaths. As with breast cancer, surgical resection, chemotherapy, radiation therapy, and immunotherapy comprise the

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standard treatments for the majority of cases, and can result in serious, permanent side effects. We believe that direct injection of Provecta into prostate tumors may selectively ablate such tumors, and, as in the case of liver and breast tumors, may also elicit an anti-tumor immune response capable of eradicating distant metastases. Since trans-urethral ultrasound, guided fine-needle biopsy and immunotherapy, along with brachytherapy implantation, are becoming routine procedures for diagnosis and treatment of these cancers, we believe that localized destruction of suspected tumors through direct injection of Provecta can become a primary treatment. We are evaluating options for initiating clinical studies of direct injection of Provecta into prostate tumors, and expect to formulate final plans based on results from clinical studies of our indications for Provecta in the treatment of liver and breast cancer.

Medical Devices

We are developing medical devices to address two major markets:

- o cosmetic treatments, such as reduction of wrinkles and elimination of spider veins and other cosmetic blemishes; and
- o therapeutic uses, including photoactivation of Xantryl other prescription drugs and non-surgical destruction of certain skin cancers.

We expect to develop medical devices through partnerships with third-party device manufacturers or, if appropriate opportunities arise, through acquisition of one or more device manufacturers.

Photoactivation. Our clinical tests of Xantryl for dermatology have, up to the present, utilized a number of commercially available lasers for activation of the drug. This approach has several advantages, including the leveraging of an extensive base of installed devices present throughout the pool of potential physician-adopters for Xantryl; access to such a base could play an integral role in early market capture. However, since the use of such lasers, which were designed for occasional use in other types of dermatologic treatment, is potentially too cumbersome and costly for routine treatment of the large population of patients with psoriasis, we have begun investigating potential use of other types of photoactivation hardware, such as light booths. The use of such booths is consistent with current care standards in the dermatology field, and may provide a cost-effective means for addressing the needs of patients and physicians alike. We anticipate that such photoactivation hardware would be developed, manufactured, and supported in conjunction with one or more third-party device manufacturer.

Melanoma. A high priority in our medical devices field is the development of a laser-based product for treatment of melanoma. We continue to conduct extensive research on ocular melanoma at the Massachusetts Eye and Ear Infirmary (a teaching affiliate of Harvard Medical School) using a new laser treatment that may offer significant advantage over current treatment options. A single quick non-invasive treatment of ocular melanoma tumors in a rabbit model resulted in elimination of over 90% of tumors, and may afford significant advantage over invasive alternatives, such as surgical excision, enucleation, or radiotherapy implantation. Ocular melanoma is rare, with approximately 2,000 new cases annually in the U.S. However, we believed that our extremely successful results could be extrapolated to treatment of primary melanomas of the skin, which have an incidence of over 52,000 new cases annually in the U.S. and a 13% five-year survival rate after metastasis of the tumor. We have performed similar laser treatments on large (averaging approximately 3 millimeters thick) cutaneous melanoma tumors implanted in mice, and have been able to eradicate over 90% of these pigmented skin tumors with a single treatment. Moreover, we have shown that this treatment stimulates an anti-tumor immune response that may lead to improved outcome at both the treatment site and at sites of distant metastasis. From these results, we believe that a device for laser treatment of

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primary melanomas of the skin and eye is nearly ready for human studies. We anticipate partnering with a medical device manufacturer to bring it to market

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in reliance on a 510(k) notification. For more information about the 510(k) notification process, see "Federal Regulation of Therapeutic Products" below.

Research and Development

We continue to actively develop projects that are product directed and are attempting to conserve available capital and achieve full capitalization of our company through equity and convertible debt offerings, generation of product revenues, and other means. All ongoing research and development activities are directed toward supporting our OTC product launches, our current product development and maintaining our intellectual property portfolio.

Production

We have determined that the most efficient use of our capital in producing OTC products is to contract production with experienced entities having previous success in economically producing such products. We have ongoing relationships with two OTC product manufacturers, EXAL, Inc. and 220 Laboratories, Inc., and several other OTC service vendors that will manufacture, package, warehouse and ship our OTC products. We do not have written agreements with any of our manufacturers or vendors.

Sales

Our first commercially available products are directed into the OTC market, as these products pose minimal or no regulatory compliance barriers to market introduction. In this fashion, we believe that we can diminish the risk of regulatory bars to the introduction of products and minimize the time required to begin generating revenues from product sales. At the same time, we continue to develop higher-margin prescription pharmaceuticals and medical devices, which have longer development and regulatory approval cycles.

We are commencing limited sales of Pure-ific, our antibacterial hand spray. We sold small amounts of this product during 2004. We will continue to seek additional markets for our products through existing distributorships that market and distribute medical products, ethical pharmaceuticals, and OTC products for the professional and consumer marketplaces.

In addition to developing and selling products ourselves, we are negotiating actively with a number of potential licensees for several of our intellectual properties, including patents and related technologies. To date, we have not yet entered into any licensing agreements; however, we anticipate consummating one or more such licenses in the future.

Intellectual Property

Patents

We hold a number of U.S. patents covering the technologies we have developed and are continuing to develop for the production of prescription drugs, medical devices and OTC pharmaceuticals, including those identified in the following table:

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| U.S. Patent No. ----- | Title ----- | Issue Date ----- | E --- |
|--------------------------|--|---------------------|----------|
| 5,829,448 | Method for improved selectivity in photo-activation of molecular agents | November 3, 1998 | Oc |
| 5,832,931 | Method for improved selectivity in photo-activation and detection of molecular diagnostic agents | November 10, 1998 | Oc |
| 5,998,597 | Method for improved selectivity in photo-activation of molecular agents | December 7, 1999 | Oc |

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| U.S. Patent No. ----- | Title ----- | Issue Date ----- | EX --- |
|--------------------------|--|---------------------|-----------|
| 6,042,603 | Method for improved selectivity in photo-activation of molecular agents | March 28, 2000 | Oc |
| 6,331,286 | Methods for high energy phototherapeutics | December 18, 2001 | De |
| 6,451,597 | Method for enhanced protein stabilization and for production of cell lines useful for production of such stabilized proteins | September 17, 2002 | Ap |
| 6,468,777 | Method for enhanced protein stabilization and for production of cell lines useful for production of such stabilized proteins | October 22, 2002 | Ap |
| 6,493,570 | Method for improved imaging and photodynamic therapy | December 10, 2002 | De |
| 6,495,360 | Method for enhanced protein stabilization and for production of cell lines useful for production of such stabilized proteins | December 17, 2002 | Ap |
| 6,519,076 | Methods and apparatus for optical imaging | February 11, 2003 | Oc |
| 6,525,862 | Methods and apparatus for optical imaging | February 25, 2003 | Oc |
| 6,541,223 | Method for enhanced protein stabilization and for production of cell lines useful for production of such stabilized proteins | April 1, 2003 | Ap |

We continue to pursue patent applications on numerous other developments we believe to be patentable. We consider our issued patents, our pending patent applications and any patentable inventions which we may develop to be extremely valuable assets of our business.

Trademarks

We own the following trademarks used in this document: Xantryl(TM), Provecta(TM), GloveAid(TM), and Pure-ific(TM) (including Pure-ific(TM) and

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Pure-ific(TM) Kids). We also own the registered trademark PulseView(R). Trademark rights are perpetual provided that we continue to keep the mark in use. We consider these marks, and the associated name recognition, to be valuable to our business.

Material Transfer Agreement

We have entered into a Material Transfer Agreement dated as of July 31, 2003 with Schering-Plough Animal Health Corporation, which we refer to as "SPA", the animal-health subsidiary of Schering-Plough Corporation, a major international pharmaceutical company. We refer to this agreement in this report as the "Material Transfer Agreement." Under the Material Transfer Agreement, we will provide SPA with access to some of our patented technologies to permit SPA to evaluate those technologies for use in animal-health applications. If SPA determines that it can commercialize our technologies, then the Material Transfer Agreement obligates us and SPA to enter into a license agreement providing for us to license those technologies to SPA in exchange for progress payments upon the achievement of goals. The Material Transfer Agreement covers four U.S. patents that cover biological material manufacturing technologies (i.e., biotech related). The Material Transfer Agreement continues indefinitely, unless SPA terminates it by giving us notice or determines that it does not wish to secure from us a license for our technologies. The Material Transfer Agreement can also be terminated by either of us in the event the other party breaches the agreement and does not cure the breach within 30 days of notice from the other party. We can give you no assurance that SPA will determine that it can commercialize our technologies or that the goals required for us to obtain progress payments from SPA will be achieved.

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Competition

In general, the pharmaceutical industry is intensely competitive, characterized by rapid advances in products and technology. A number of companies have developed and continue to develop products that address the areas we have targeted. Some of these companies are major pharmaceutical companies that are international in scope and very large in size, while others are niche players that may be less familiar but have been successful in one or more areas we are targeting. Existing or future pharmaceutical, device, or other competitors may develop products that accomplish similar functions to our technologies in ways that are less expensive, receive faster regulatory approval, or receive greater market acceptance than our products. Many of our competitors have been in existence for considerably longer than we have, have greater capital resources, broader internal structure for research, development, manufacturing and marketing, and are in many ways further along in their respective product cycles.

At present, our most direct competitors are smaller companies that are exploiting niches similar to ours. In the field of photodynamic therapy, one competitor, QLT, Inc., has received FDA approval for use of its agent Photofrin(R) for treatment of several niche cancer indications, and has a second product, Visudyne(R), approved for treatment of certain forms of macular degeneration. Another competitor in this field, Dusa Pharmaceuticals, Inc. recently received FDA approval of its photodynamic product Levulan(R) Kerastik(R) for treatment of actinic keratosis. We believe that QLT and Dusa, among other competitors, have established a working commercial model in dermatology and oncology, and that we can benefit from this model by offering products that, when compared to our competitors' products, afford superior safety and performance, greatly reduced side effects, improved ease of use, and lower cost, compared to those of our competitors.

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While it is possible that eventually we may compete directly with major pharmaceutical companies, we believe it is more likely that we will enter into joint development, marketing, or other licensure arrangements with such competitors.

We also have a number of market areas in common with traditional skincare cosmetics companies, but in contrast to these companies, our products are based on unique, proprietary formulations and approaches. For example, we are unaware of any products in our targeted OTC skincare markets that are similar to our GloveAid and Pure-ific products. Further, proprietary protection of our products may help limit or prevent market erosion until our patents expire. Federal Regulation of Therapeutic Products

All of the prescription drugs and medical devices we currently contemplate developing will require approval by the FDA prior to sales within the United States and by comparable foreign agencies prior to sales outside the United States. The FDA and comparable regulatory agencies impose substantial requirements on the manufacturing and marketing of pharmaceutical products and medical devices. These agencies and other entities extensively regulate, among other things, research and development activities and the testing, manufacturing, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our proposed products. While we attempt to minimize and avoid significant regulatory bars when formulating our products, some degree of regulation from these regulatory agencies is unavoidable. Some of the things we do to attempt to minimize and avoid significant regulatory bars include the following:

- o Using chemicals and combinations already allowed by the FDA;
- o Carefully making product performance claims to avoid the need for regulatory approval;
- o Using drugs that have been previously approved by the FDA and that have a long history of safe use;
- o Using chemical compounds with known safety profiles; and

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- o In many cases, developing OTC products which face less regulation than prescription pharmaceutical products.

The regulatory process required by the FDA, through which our drug or device products must pass successfully before they may be marketed in the U.S., generally involves the following:

- o Preclinical laboratory and animal testing;
- o Submission of an application that must become effective before clinical trials may begin;
- o Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication; and
- o FDA approval of the application to market a given product for a given indication.

For pharmaceutical products, preclinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product. Where

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appropriate (for example, for human disease indications for which there exist inadequate animal models), we will attempt to obtain preliminary data concerning safety and efficacy of proposed products using carefully designed human pilot studies. We will require sponsored work to be conducted in compliance with pertinent local and international regulatory requirements, including those providing for Institutional Review Board approval, national governing agency approval and patient informed consent, using protocols consistent with ethical principles stated in the Declaration of Helsinki and other internationally recognized standards. We expect any pilot studies to be conducted outside the United States; but if any are conducted in the United States, they will comply with applicable FDA regulations. Data obtained through pilot studies will allow us to make more informed decisions concerning possible expansion into traditional FDA-regulated clinical trials.

If the FDA is satisfied with the results and data from preclinical tests, it will authorize human clinical trials. Human clinical trials typically are conducted in three sequential phases which may overlap. Each of the three phases involves testing and study of specific aspects of the effects of the pharmaceutical on human subjects, including testing for safety, dosage tolerance, side effects, absorption, metabolism, distribution, excretion and clinical efficacy.

Phase 1 clinical trials include the initial introduction of an investigational new drug into humans. These studies are closely monitored and may be conducted in patients, but are usually conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. While the FDA can cause us to end clinical trials at any phase due to safety concerns, Phase 1 clinical trials are primarily concerned with safety issues. We also attempt to obtain sufficient information about the drug's pharmacokinetics and pharmacological effects during Phase 1 clinical trial to permit the design of well-controlled, scientifically valid, Phase 2 studies.

Phase 1 studies also evaluate drug metabolism, structure-activity relationships, and the mechanism of action in humans. These studies also determine which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects included in Phase 1 studies varies with the drug, but is generally in the range of twenty to eighty.

Phase 2 clinical trials include the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving several hundred people.

Phase 3 studies are expanded controlled and uncontrolled trials. They are

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performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually include several hundred to several thousand people.

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Applicable medical devices can be cleared for commercial distribution through a notification to the FDA under Section 510(k) of the applicable statute. The 510(k) notification must demonstrate to the FDA that the device is as safe and effective and substantially equivalent to a legally marketed or classified device that is currently in interstate commerce. Such devices may not require detailed testing. Certain high-risk devices that sustain human life, are of substantial importance in preventing impairment of human health, or that present a potential unreasonable risk of illness or injury, are subject to a more comprehensive FDA approval process initiated by filing a premarket approval, also known as a "PMA," application (for devices) or accelerated approval (for drugs).

We have established a core clinical development team and have been working with outside FDA consultants to assist us in developing product-specific development and approval strategies, preparing the required submittals, guiding us through the regulatory process, and providing input to the design and site selection of human clinical studies. Historically, obtaining FDA approval for photodynamic therapies has been a challenge. Wherever possible, we intend to utilize lasers or other activating systems that have been previously approved by the FDA to mitigate the risk that our therapies will not be approved by the FDA. The FDA has considerable experience with lasers by virtue of having reviewed and acted upon many 510(k) and premarket approval filings submitted to it for various photodynamic and non-photodynamic therapy laser applications, including a large number of cosmetic laser treatment systems used by dermatologists.

The testing and approval process requires substantial time, effort, and financial resources, and we may not obtain FDA approval on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later stage clinical trials. The FDA or the research institution sponsoring the trials may suspend clinical trials or may not permit trials to advance from one phase to another at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Once issued, the FDA may withdraw a product approval if we do not comply with pertinent regulatory requirements and standards or if problems occur after the product reaches the market. If the FDA grants approval of a product, the approval may impose limitations, including limits on the indicated uses for which we may market a product. In addition, the FDA may require additional testing and surveillance programs to monitor the safety and/or effectiveness of approved products that have been commercialized, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Further, later discovery of previously unknown problems with a product may result in restrictions on the product, including its withdrawal from the market.

Marketing our products abroad will require similar regulatory approvals by equivalent national authorities and is subject to similar risks. To expedite development, we may pursue some or all of our initial clinical testing and approval activities outside the United States, and in particular in those nations where our products may have substantial medical and commercial relevance. In some such cases any resulting products may be brought to the U.S. after substantial offshore experience is gained. Accordingly, we intend to pursue any such development in a manner consistent with U.S. standards so that the resultant development data is maximally applicable for potential FDA approval.

OTC products are subject to regulation by the FDA and similar regulatory agencies but the regulations relating to these products are much less stringent than those relating to prescription drugs and medical devices. The types of OTC products developed and sold by us only require that we follow cosmetic rules relating to labeling and the claims that we make about our product. The process for obtaining approval of prescription drugs with the FDA does not apply to the OTC products which we sell. The FDA can, however, require us to stop selling our

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product if we fail to comply with the rules applicable to our OTC products.

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Personnel

Executive Officers

As of March 17, 2005, our executive officers are:

H. Craig Dees, Ph.D., 53, Chief Executive Officer. Dr. Dees has served as our Chief Executive Officer and as a member of our Board of Directors since we acquired PPI on April 23, 2002. Before joining us, from 1997 to 2002 he served as senior member of the management team of Photogen Technologies, Inc., including serving as a member of the Board of Directors of Photogen from 1997 to 2000. Prior to joining Photogen, Dr. Dees served as a Group Leader at the Oak Ridge National Laboratory (ORNL), and as a senior member of the management teams of LipoGen Inc., a medical diagnostic company which used genetic engineering technologies to manufacture and distribute diagnostic assay kits for auto-immune diseases, and TechAmerica Group Inc., now a part of Boehringer Ingelheim Vetmedica, Inc., the U.S. animal health subsidiary of Boehringer Ingelhem GmbH, an international chemical and pharmaceutical company headquartered in Germany. He has developed numerous products in a broad range of areas, including ethical vaccines, human diagnostics, cosmetics and OTC pharmaceuticals, and has set several regulatory precedents in licensing and developing biotechnology-derived products. For example, Dr. Dees developed and commercialized the world's first live viral vaccine produced by recombinant DNA technologies and licensed the first recombinant antigen human diagnostic assay using a FDA Class II licensure. While at TechAmerica he developed and obtained USDA approval for the first in vitro assay for releasing "killed" viral vaccines. Dr. Dees also has licensed successfully a number of proprietary cosmetic products and formulated strategic planning for developing cosmetic companies. He earned a Ph.D. in Molecular Virology from the University of Wisconsin - Madison in 1984.

Timothy C. Scott, Ph.D., 47, President. Dr. Scott has served as our President and as a member of our Board of Directors since we acquired PPI on April 23, 2002. Prior to joining us, Dr. Scott was as a senior member of the Photogen management team from 1997 to 2002, including serving as Photogen's Chief Operating Officer from 1999 to 2002, as a director of Photogen from 1997 to 2000, and as interim CEO for a period in 2000. Before joining Photogen, he served as senior management of Genase LLC, a developer of enzymes for fabric treatment, and held senior research and management positions at ORNL. Dr. Scott has been involved in developing numerous high-tech innovations in a broad range of areas, including separations science, biotechnology, biomedical, and advanced materials. He has licensed several of his innovations to the oil and gas and biotechnology industries. As Director of the Bioprocessing R&D Center at ORNL, Dr. Scott achieved a national presence in the area of use of advanced biotechnology for the production of energy, fuels, and chemicals. He earned a Ph.D. in Chemical Engineering from the University of Wisconsin - Madison in 1985.

Eric A. Wachter, Ph.D., 42, Vice President - Pharmaceuticals. Dr. Wachter has served as our Vice President - Pharmaceuticals and as a member of our Board of Directors since we acquired PPI on April 23, 2002. Prior to joining us, from 1997 to 2002 he was a senior member of the management team of Photogen, including serving as Secretary and a director of Photogen since 1997 and as Vice President and Secretary and a director of Photogen since 1999. Prior to joining Photogen, Dr. Wachter served as a senior research staff member with ORNL. Starting during his affiliation with Photogen, Dr. Wachter has been extensively involved in pre-clinical development and clinical testing of pharmaceuticals and medical device systems, as well as with coordination and filing of patents. He earned a Ph.D. in Chemistry from the University of Wisconsin - Madison in 1988.

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Peter R. Culpepper, CPA, MBA, 45, Chief Financial Officer. Mr. Culpepper was appointed to serve as our Chief Financial Officer in February 2004. Previously, Mr. Culpepper served as Chief Financial Officer for Felix Culpepper International, Inc. from 2001 to 2004; was a Registered Representative with AXA Advisors, LLC from 2002 to 2003; has served as Chief Accounting Officer and Corporate Controller for Neptec, Inc. from 2000 to 2001; has served in various Senior Director positions with Metromedia Affiliated Companies from 1998 to 2000; has served in various Senior Director and other financial positions with Paging Network, Inc. from 1993 to 1998; and has served in a variety of financial roles in public accounting and industry from 1982 to 1993. He earned an MBA in Finance from the University of Maryland - College Park in 1992. He earned an

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undergraduate degree from the College of William and Mary - Williamsburg, Virginia in 1982. He is a licensed Certified Public Accountant in both Tennessee and Maryland and is a faculty member with the University of Phoenix.

Employees

We currently employ four persons, all of whom are full-time employees.

Available Information

Provectus Pharmaceuticals, Inc. is subject to the informational requirements of the Securities Exchange Act of 1934, as amended, which we refer to as the "Exchange Act." To comply with those requirements, we file annual reports, quarterly reports, periodic reports and other reports and statements with the Securities and Exchange Commission, which we refer to as the "SEC." You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room, at 450 Fifth Street, N.W., Washington, D.C. 20549. You can obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site at <http://www.sec.gov>, from which you can access electronic copies of materials we file with the SEC.

Our Internet address is <http://www.pvct.com>. We have made available, through a link to the SEC's Web site, electronic copies of the materials we file with the SEC (including our annual reports on Form 10-KSB, our quarterly reports on Form 10-QSB, our current reports on Form 8-K, the Section 16 reports filed by our executive officers, directors and 10% shareholders and amendments to those reports). To receive paper copies of our SEC materials, please contact us by U.S. mail, telephone, facsimile or electronic mail at the following address:

Provectus Pharmaceuticals, Inc.
Attention: President
7327 Oak Ridge Highway, Suite A
Knoxville, TN 37931
Telephone: 865/769-4011
Facsimile: 865/769-4013
Electronic mail: info@pvct.com

Item 2. Description of Property.

We currently lease approximately 4,000 square feet of space outside of Knoxville, Tennessee for our corporate office and operations. Our monthly rental charge for these offices is approximately \$2,800 per month, and the lease is renewed on a month-to-month basis. We believe that these offices generally are adequate for our needs currently and in the immediate future.

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Item 3. Legal Proceedings.

From time to time, we are party to litigation or other legal proceedings that we consider to be a part of the ordinary course of our business. At present, we are not involved in any legal proceedings nor are we party to any pending claims that we believe could reasonably be expected to have a material adverse effect on our business, financial condition, or results of operations.

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

During the three months ended December 31, 2004, we did not submit any matters to a vote of our stockholders.

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Part II

Item 5. Market for Common Equity and Related Stockholder Matters.

Market Information and Holders

Quotations for our common stock are reported on the OTC Bulletin Board under the symbol "PVCT." The following table sets forth the range of high and low bid information for the periods indicated since January 1, 2002:

| | High | Low |
|---|--------|--------|
| | ---- | ---- |
| 2003 | | |
| First Quarter (January 1 to March 31) | \$0.60 | \$0.26 |
| Second Quarter (April 1 to June 30) | \$1.01 | \$0.21 |
| Third Quarter (July 1 to September 30) | \$0.60 | \$0.20 |
| Fourth Quarter (October 1 to December 31) | \$2.00 | \$0.22 |
| 2004 | | |
| First Quarter (January 1 to March 31) | \$1.70 | \$0.80 |
| Second Quarter (April 1 to June 30) | \$1.51 | \$0.85 |
| Third Quarter (July 1 to September 30) | \$1.68 | \$0.52 |
| Fourth Quarter (October 1 to December 31) | \$0.82 | \$0.47 |

The closing price for our common stock on March 17, 2005 was \$0.97. High and low quotation information was obtained from data provided by Yahoo! Inc. Quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not reflect actual transactions.

As of March 17, 2005, we had 1,822 shareholders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently plan to retain future earnings, if any, to finance the growth and development of our business and do not anticipate paying any cash dividends in the foreseeable future. We may incur indebtedness in the future which may prohibit or effectively restrict the payment of dividends, although we have no

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current plans to do so. Any future determination to pay cash dividends will be at the discretion of our board of directors.

Recent Sales of Unregistered Securities

During the year ended December 31, 2004, we did not sell any securities which were not registered under the Securities Act of 1933, as amended, which we refer to as the "Securities Act," except on November 16, 2004, the Company completed a private placement transaction with 14 accredited investors, pursuant to which we sold 530,166 shares of our common stock at a purchase price of \$0.75 per share, for an aggregate purchase price of \$397,625 pursuant to Securities Purchase Agreements with each investor. In connection with the sale of the common stock, we also issued warrants (the "Warrants") to the investors to purchase up to 795,249 shares of our common stock at an exercise price of \$1.00 per share. We paid \$39764 to Venture Catalyst, LLC as placement agent for this transaction. We believe that this offering was exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act") by reason of Rule 506

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of Regulation D and Section 4(2) of the Securities Act, based upon the fact that the offer and issuance of the common stock and warrants satisfied all the terms and conditions of Rules 501 and 502 of the Securities Act, the investors are financially sophisticated and had access to complete information concerning us and acquired the securities for investment and not with a view to the distribution thereof. Proceeds will be used for general corporate purposes.

Pursuant to an agreement dated November 26, 2004 between us and Gryffindor, we issued Gryffindor a Second Amended and Restated Senior Secured Convertible Note dated November 26, 2004 in the amended principal amount of \$1,185,959. The amended note bears interest at 8% per annum, payable quarterly in arrears, is due and payable in full on November 26, 2005, and amends and restated the amended note in its entirety. As with the prior notes, our obligations under the amended note are secured by a first priority security interest in all of our assets, including the assets held by our Xantech and Pure-ific subsidiaries. Subject to certain exceptions, the amended note is convertible into shares of our common stock beginning on the November 26, 2004; the principal amount of the note is convertible at the rate of one share of common stock for each \$0.73655655 of principal converted, while accrued but unpaid interest on the note is convertible at the rate of one share of common stock for each \$0.55 of accrued but unpaid interest converted. We relied on an exemption from registration pursuant to Section 4(2) of the Securities Act, based on the issuance of the amended note, and the issuance of the shares of common stock issuable upon conversion of the amended note, to a limited number of purchasers in a transaction not involving any general solicitation or general advertising.

Item 6. Management's Discussion and Analysis or Plan of Operation.

The following discussion is intended to assist in the understanding and assessment of significant changes and trends related to our results of operations and our financial condition together with our consolidated subsidiaries. This discussion and analysis should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-KSB. Historical results and percentage relationships set forth in the statement of operations, including trends which might appear, are not necessarily indicative of future operations.

CAPITAL STRUCTURE

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Our ability to continue as a going concern has become reasonably assured due to our financing in June, July, and November 2004, as well as March 2005. However, our ongoing operations continue to be dependent upon our ability to raise capital.

We plan to implement our integrated business plan, including execution of the next phases in clinical development of our pharmaceutical products and full resumption of research programs for new research initiatives.

We intend to proceed as rapidly as possible with the development of OTC products that can be sold with a minimum of regulatory compliance and with the further development of revenue sources through licensing of our existing intellectual property portfolio. Although we believe that there is a reasonable basis for our expectation that we will become profitable due to revenues from OTC product sales, we cannot assure you that we will be able to achieve, or maintain, a level of profitability sufficient to meet our operating expenses.

Our current plans include continuing to operate with our four employees during the immediate future, but we anticipate adding some part-time employees during the next year. Our current plans also include minimal purchases of new property, plant and equipment, and significantly increased research and development.

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PLAN OF OPERATION

With the reorganization of Provectus and PPI and the acquisition and integration into the company of Valley and Pure-ific, we believe we have obtained a unique combination of OTC products and core intellectual properties. This combination represents the foundation for an operating company that we believe will provide both profitability and long-term growth. In 2005, through careful control of expenditures, increasing sales of OTC products, and issuance of debt and equity, we plan to build on that foundation to increase shareholder value.

In the short term, we intend to develop our business by marketing, manufacturing, and distributing our existing OTC products, principally GloveAid and Pure-ific. In the longer term, we expect to continue the process of developing, testing and obtaining the approval of the U. S. Food and Drug Administration of prescription drugs and medical devices. Additionally, we intend to restart our research programs that will identify additional conditions that our intellectual properties may be used to treat and additional treatments for those and other conditions.

We are in the planning phase for the major research and development projects, and therefore do not have estimated completion dates, completion costs and capital requirements for these projects. The reason we do not have this information available is because we have not completed our planning process. Since there is no defined schedule for completing these development projects, there are no defined consequences if they are not completed timely. Research and development costs comprising the total of \$1,291,817 for 2004 included depreciation expense of \$121,811, consulting of \$493,305, lab expense of \$10,958, insurance of \$74,059, legal expense of \$127,775, office and other expense of \$3,751, payroll of \$431,068, rent and utilities of \$20,533, and taxes and fees of \$8,557. The research and development costs comprising a total of \$724,924 for 2003 included depreciation expense of \$218,082 (\$10,233 of depreciation expense is recorded in general and administrative), consulting of \$49,198, lab expense of \$12,800, insurance of \$10,153, legal expense of \$130,271, office and other expense of \$2,008, payroll of \$252,042, rent and utilities of \$38,057, and taxes and fees of \$12,313.

CASH FLOW

As of March 30, 2005, we held approximately \$1,600,000 in cash in escrow for our benefit. We anticipate these funds will be released from the escrow shortly. At our current cash expenditure rate, this amount will be sufficient to meet our needs for the foreseeable future. We already have begun to increase our expenditure rate by accelerating some of our research programs for new research initiatives; in addition, we are seeking to improve our cash flow by increasing sales of OTC products. However, we cannot assure you that we will be successful in increasing sales of OTC products. Moreover, even if we are successful in improving our current cash flow position, we nonetheless will require additional funds to meet our long-term needs. We anticipate these funds will come from the proceeds of private placements or public offerings of debt or equity securities.

CAPITAL RESOURCES

As noted above, our present cash flow is currently sufficient to meet our short-term operating needs for initial production and distribution of OTC products in order to achieve meaningful sales volumes. Excess cash will be used to finance the next phases in clinical development of our pharmaceutical products and resumption of our currently suspended research programs. We anticipate that the majority of the funds for our operating and development needs in 2005 will come from the proceeds of private placements or public offerings of debt or equity securities. While we believe that we have a reasonable basis for our expectation that we will be able to raise additional funds, we cannot assure you that we will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to shareholders. For further information on funding sources, please see the notes to our financial statements included in this report.

Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), "Shared-Based Payment," which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends SFAS No. 95, "Statement of Cash Flows." Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. This revised standard will be effective for us beginning with the third quarter in 2005.

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB 25 intrinsic value method and, as such, generally recognizes no compensation cost for Employee stock options. Accordingly, the adoption of SFAS No. 123(R)'s fair value method will have an impact on the result of operations, although it will have no impact on the overall financial position. The impact of the modified prospective adoption of SFAS No. 123(R) cannot be estimated at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net income and earnings per share.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs: an amendment of ARB No. 43, Chapter 4," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151

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is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not believe the provisions of SFAS No. 151, when applied, will have a material impact on the financial position or results of operations.

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Item 7. Financial Statements.

Our consolidated financial statements, together with the report thereon of BDO Seidman LLP, independent accountants, are set forth on the pages of this Annual Report on Form 10-KSB indicated below.

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|---|------|
| | ---- |
| Report of Independent Registered Public Accounting Firm | F-1 |
| Consolidated Balance Sheets as of December 31, 2004 and December 31, 2003 | F-2 |
| Consolidated Statements of Operations for the years ended December 31, 2004 and 2003 | F-3 |
| Consolidated Statements of Shareholders' Equity for the years ended December 31, 2004 and 2003 | F-4 |
| Consolidated Statements of Cash Flows for the year ended December 31, 2004 and 2003 | F-5 |
| Notes to Consolidated Financial Statements | F-7 |

Forward-Looking Statements

This Annual Report on Form 10-KSB contains forward-looking statements regarding, among other things, our anticipated financial and operating results. Forward-looking statements reflect our management's current assumptions, beliefs, and expectations. Words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," and similar expressions are intended to identify forward-looking statements. While we believe that the expectations reflected in our forward-looking statements are reasonable, we can give no assurance that such expectations will prove correct. Forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from the future results, performance, or achievements expressed in or implied by any forward-looking statement we make. Some of the relevant risks and uncertainties that could cause our actual performance to differ materially from the forward-looking statements contained in this report are discussed below under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-KSB. We caution investors that these discussions of important risks and uncertainties are not exclusive, and our business may be subject to other risks and uncertainties which are not detailed there.

Investors are cautioned not to place undue reliance on our forward-looking statements. We make forward-looking statements as of the date on which this Annual Report on Form 10-KSB is filed with the SEC, and we assume no obligation to update the forward-looking statements after the date hereof whether as a result of new information or events, changed circumstances, or otherwise, except as required by law.

Risk Factors

Our business is subject to various risks, including those described below. You should carefully consider these risk factors, together with all of the other information included in this Annual Report on Form 10-KSB. Any of these risks could materially adversely affect our business, operating results and financial condition:

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Our technologies are in early stages of development. We have generated minimal initial revenues from sales and operations in 2004, but we do not expect to generate sufficient revenues to enable us to be profitable for several calendar quarters. We require additional funding to continue initial production and distribution of OTC products in order to achieve meaningful sales volumes. In addition, we must raise substantial additional funds in order to fully

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implement our integrated business plan, including execution of the next phases in clinical development of our pharmaceutical products and resumption of research programs currently suspended. We estimate that our existing capital resources will be sufficient to fund our current and planned operations.

Ultimately, we must achieve profitable operations if we are to be a viable entity. We intend to proceed as rapidly as possible with the development of OTC products that can be sold with a minimum of regulatory compliance and with the development of revenue sources through licensing of our existing intellectual property portfolio. We cannot assure you that we will be able to raise sufficient capital to sustain operations before we can commence revenue generation or that we will be able to achieve, or maintain, a level of profitability sufficient to meet our operating expenses.

Because of our limited operations and the fact that we are currently generating limited revenue, we may be unable to pay our debts when they become due.

As of December 31, 2004, we had \$2,084,959 in debt, net of a debt discount of \$411,210 and \$43,671 of accrued interest on our balance sheet, consisting of \$1,185,959 in principal and \$9,224 in accrued but unpaid interest owed to Gryffindor pursuant to the Note; \$750,000 in principal and \$19,011 in accrued interest owed to the holders of our debentures which has been authorized to be paid on March 30, 2005 and \$149,000 in principal and \$15,436 in accrued interest owed to Dr. Wachter. The amounts due to Gryffindor are due in November 2005, the amounts due in equal installments to the holders of our debentures are due in July and October 2007, and the amounts due to Dr. Wachter are due in 2009. Because of the convertible nature of the debt owed to Gryffindor and to the holders of the convertible debentures, we may not have to repay this debt if the debt is converted into shares of our common stock. However, we can not assure you that this debt will be converted into common stock and we may have to repay this indebtedness. Our ability to satisfy our current debt service obligations and any additional obligations we might incur will depend upon our future financial and operating performance, which, in turn, is subject to prevailing economic conditions and financial, business, competitive, legislative and regulatory factors, many of which are beyond our control. We cannot assure you that our operating results, cash flow and capital resources will be sufficient for payment of our debt service and other obligations in the future.

We will need additional capital to conduct our operations and develop our products, and our ability to obtain the necessary funding is uncertain.

We estimate that our existing capital resources will be sufficient to fund our current and planned operations; however, we may need additional capital. We have based this estimate on assumptions that may prove to be wrong, and we cannot assure that estimates and assumptions will remain unchanged. For example, we are currently assuming that we will continue to operate without any significant staff or other resources expansion. We intend to acquire additional funding through public or private equity financings or other financing sources that may be available. Additional financing may not be available on acceptable terms, or at all. As discussed in more detail below, additional equity financing could result in significant dilution to shareholders. Further, in the event that

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additional funds are obtained through licensing or other arrangements, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our business, and may impair the value of our patents and other intangible assets.

Existing shareholders may face dilution from our financing efforts.

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We must raise additional capital from external sources to execute our business plan. We plan to issue debt securities, capital stock, or a combination of these securities. We may not be able to sell these securities, particularly under current market conditions. Even if we are successful in finding buyers for our securities, the buyers could demand high interest rates or require us to agree to onerous operating covenants, which could in turn harm our ability to operate our business by reducing our cash flow and restricting our operating activities. If we were to sell our capital stock, we might be forced to sell shares at a depressed market price, which could result in substantial dilution to our existing shareholders. In addition, any shares of capital stock we may issue may have rights, privileges, and preferences superior to those of our common shareholders.

The prescription drug and medical device products in our internal pipeline are at an early stage of development, and they may fail in subsequent development or commercialization.

We are continuing to pursue clinical development of our most advanced pharmaceutical drug products, Xantryl and Provecta, for use as treatments for specific conditions. These products and other pharmaceutical drug and medical device products that we are currently developing will require significant additional research, formulation and manufacture development, and pre-clinical and extensive clinical testing prior to regulatory licensure and commercialization. Pre-clinical and clinical studies of our pharmaceutical drug and medical device products under development may not demonstrate the safety and efficacy necessary to obtain regulatory approvals. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in earlier trials. Pharmaceutical drug and medical device products that appear to be promising at early stages of development may not reach the market or be marketed successfully for a number of reasons, including the following:

- o a product may be found to be ineffective or have harmful side effects during subsequent pre-clinical testing or clinical trials;
- o a product may fail to receive necessary regulatory clearance;
- o a product may be too difficult to manufacture on a large scale;
- o a product may be too expensive to manufacture or market;
- o a product may not achieve broad market acceptance;
- o others may hold proprietary rights that will prevent a product from being marketed; or
- o others may market equivalent or superior products.

We do not expect any pharmaceutical drug products or medical device products we are developing to be commercially available for at least several years, if at all. Our research and product development efforts may not be successfully completed and may not result in any successfully commercialized products. Further, after commercial introduction of a new product, discovery of problems through adverse event reporting could result in restrictions on the

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product, including withdrawal from the market and, in certain cases, civil or criminal penalties.

Our OTC products are at an early stage of introduction, and we cannot be sure that they will be widely accepted in the marketplace or that we will have adequate capital to market and distribute these products which are an important factor in the future success of our business.

We recently have begun marketing GloveAid and Pure-ific, our first two OTC products, on a limited basis. We have recognized minimal revenue from these products, as the sales of these products have not been material. In order for these products to become commercially successful, we must increase significantly our distribution of them. Increasing distribution of these products requires, in turn, that we or distributors representing us increase marketing of these products. In view of our limited financial resources, we may be unable to afford

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increases in our marketing of our OTC products sufficient to improve our distribution of our products. Even if we can and do increase our marketing of our OTC products, we cannot give you any assurances that we can successfully increase our distribution of our products.

If we do begin increasing our distribution of our OTC products, we must increase our production of these products in order to fill our distribution channels. Increased production will require additional financial resources that we do not have at present. Additionally, we may succeed in increasing production without succeeding in increasing sales, which could leave us with excess, possibly unsaleable, inventory.

If we are unable to successfully introduce, market and distribute these products, our business, financial condition, results of operations and cash flows could be materially adversely affected.

Competition in the prescription drug, medical device and OTC pharmaceuticals markets is intense, and we may be unable to succeed if our competitors have more funding or better marketing.

The pharmaceutical and biotechnology industries are intensely competitive. Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in research efforts related to treatment of dermatological conditions or cancers of the skin, liver and breast, which could lead to the development of products or therapies that could compete directly with the prescription drug, medical device and OTC products that we are seeking to develop and market.

Many companies are also developing alternative therapies to treat cancer and dermatological conditions and, in this regard, are our competitors. Many of the pharmaceutical companies developing and marketing these competing products have significantly greater financial resources and expertise than we do in:

- o research and development;
- o manufacturing;
- o preclinical and clinical testing;
- o obtaining regulatory approvals; and
- o marketing.

Smaller companies may also prove to be significant competitors,

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particularly through collaborative arrangements with large and established companies. Academic institutions, government agencies and other public and private research organizations also may conduct research, seek patent protection and establish collaborative arrangements for research, clinical development and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our programs.

In addition to the above factors, we expect to face competition in the following areas:

- o product efficacy and safety;
- o the timing and scope of regulatory consents;
- o availability of resources;
- o reimbursement coverage;
- o price; and
- o patent position, including potentially dominant patent positions of others.

As a result of the foregoing, our competitors may develop more effective or more affordable products or achieve earlier product commercialization than we do.

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Product Competition. Additionally, since our currently marketed products are generally established and commonly sold, they are subject to competition from products with similar qualities.

Our OTC product Pure-ific competes in the market with other hand sanitizing products, including in particular, the following hand sanitizers:

- o Purell (manufactured by GOJO Industries),
- o Avagard D (manufactured by 3M) and
- o a large number of generic and private-label equivalents to these market leaders.

Our OTC product GloveAid represents a new product category that has no direct competitors; however, other types of products, such as AloeTouch(R) disposable gloves (manufactured by Medline Industries) target the same market niche.

Since our prescription products Provecta and Xantryl have not yet been approved by the FDA or introduced to the marketplace, we cannot estimate what competition these products might face when they are finally introduced, if at all. We cannot assure you that these products will not face significant competition for other prescription drugs and generic equivalents.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other intellectual property our business could be harmed.

We may not be successful in securing or maintaining proprietary patent protection for our products or products and technologies we develop or license.

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In addition, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property protection, which could reduce our anticipated sales. While some of our products have proprietary patent protection, a challenge to these patents can be subject to expensive litigation. Litigation concerning patents, other forms of intellectual property and proprietary technology is becoming more widespread and can be protracted and expensive and can distract management and other personnel from performing their duties for us.

We also rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation in order to develop a competitive position. We cannot assure you that others will not independently develop substantially equivalent proprietary technology and techniques or otherwise gain access to our trade secrets and technology, or that we can adequately protect our trade secrets and technology.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other intellectual property, our business, financial condition, results of operations and cash flows could be materially adversely affected. If we infringe on the intellectual property of others, our business could be harmed.

We could be sued for infringing patents or other intellectual property that purportedly cover products and/or methods of using such products held by persons other than us. Litigation arising from an alleged infringement could result in removal from the market, or a substantial delay in, or prevention of, the introduction of our products, any of which could have a material adverse effect on our business, financial condition, or results of operations and cash flows.

If we do not update and enhance our technologies, they will become obsolete.

The pharmaceutical market is characterized by rapid technological change, and our future success will depend on our ability to conduct successful research in our fields of expertise, to discover new technologies as a result of that research, to develop products based on our technologies, and to commercialize those products. While we believe that our current technology is adequate for our

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present needs, if we fail to stay at the forefront of technological development, we will be unable to compete effectively. Our competitors are using substantial resources to develop new pharmaceutical technologies and to commercialize products based on those technologies. Accordingly, our technologies may be rendered obsolete by advances in existing technologies or the development of different technologies by one or more of our current or future competitors.

If we lose any of our key personnel, we may be unable to successfully execute our business plan.

Our business is presently managed by four key employees:

- o H. Craig Dees, Ph.D., our Chief Executive Officer;
- o Timothy C. Scott, Ph.D., our President;
- o Eric A. Wachter, Ph.D. our Vice President - Pharmaceuticals; and
- o Peter R. Culpepper, CPA, our Chief Financial Officer.

In addition to their responsibilities for management of our overall business strategy, Drs. Dees, Scott and Wachter are our chief researchers in the fields in which we are developing and planning to develop prescription drug,

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medical device and OTC products. Also, as of December 31, 2004, we owe \$156,377 in accrued but unpaid compensation to our employees. The loss of any of these key employees could have a material adverse effect on our operations, and our ability to execute our business plan might be negatively impacted. Any of these key employees may leave their employment with us if they choose to do so, and we cannot assure you that we would be able to hire similarly qualified executives if any of our key employees should choose to leave.

Because we have only four employees, our management may be unable to successfully manage our business.

In order to successfully execute our business plan, our management must succeed in all of the following critical areas:

- o Researching diseases and possible therapies in the areas of dermatology and skin care, oncology, and biotechnology;
- o Developing prescription drug, medical device and OTC products based on our research;
- o Marketing and selling developed products;
- o Obtaining additional capital to finance research, development, production and marketing of our products; and
- o Managing our business as it grows.

As discussed above, we currently have only four employees, all of whom are full-time employees. The greatest burden of succeeding in the above areas therefore falls on Drs. Dees, Scott, Wachter, and Mr. Culpepper. Focusing on any one of these areas may divert their attention from our other areas of concern and could affect our ability to manage other aspects of our business. We cannot assure you that our management will be able to succeed in all of these areas or, even if we do so succeed, that our business will be successful as a result. We anticipate adding a part-time regulatory affairs officer, a part-time lab technician and a part-time office manager within the next year. While we have not historically had difficulty in attracting employees, our small size and limited operating history may make it difficult for us to attract and retain employees in the future which could further divert management's attention from the operation of our business.

Our common stock price can be volatile because of several factors, including a limited public float.

During the twelve-month period ended December 31, 2004, the sale price of our common stock fluctuated from \$1.70 to \$0.47 per share. We believe that our

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common stock is subject to wide price fluctuations because of several factors, including:

- o absence meaningful earnings and external financing,
- o a relatively thin trading market for our common stock, which causes trades of small blocks of stock to have a significant impact on our stock price,
- o general volatility of the stock markets and the market prices of other publicly traded companies, and
- o investor sentiment regarding equity markets generally, including public perception of corporate ethics and governance and the accuracy and transparency of financial reporting.

Financings that may be available to us under current market conditions frequently involve sales at prices below the prices at which our common stock trades on the Over the Counter Electronic Bulletin Board, as well as the

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issuance of warrants or convertible debt that require exercise or conversion prices that are calculated in the future at a discount to the then market price of our common stock.

Any agreement to sell, or convert debt or equity securities into, common stock at a future date and at a price based on the then current market price will provide an incentive to the investor or third parties to sell the common stock short to decrease the price and increase the number of shares they may receive in a future purchase, whether directly from us or in the market. For example, the initial conversion rate of the debentures issued during the third and fourth quarters of 2004 is equal to the lower of (i) 80% of the average market price of our common stock for the five (5) trading days ending on the effective date of the exercise to convert or (ii) \$1.88 per share. If the average market price of our common stock is so low that it causes the conversion rate on the debentures to fall below approximately \$0.73, and if the debenture holders enforce this provision of our agreement with them, we will have to issue more shares to the debenture holders upon conversion of the debentures and the anti-dilutive provisions contained in our agreements with Gryffindor will become operative. If these anti-dilutive provisions become operative, we may be required to issue a significant number of shares of common stock to Gryffindor. We will not receive any additional proceeds from Gryffindor for the issuance of these shares of common stock. Other financings that we may obtain may contain similar provisions, and the existence of anti-dilutive provisions in some of our existing financings may make it more difficult for us to obtain financing in the future. These types of transactions which cause the issuance of our common stock in connection with the exercise or conversion of securities may result in substantial dilution to the remaining holders of our common stock.

Financings that may be available to us frequently involve high selling costs.

Because of our limited operating history, low market capitalization, thin trading volume and other factors, we have historically had to pay high costs to

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obtain financing and expect to continue to be required to pay high costs for any future financings in which we may participate. For example, our past sales of shares and our sale of the debentures have involved the payment of finder's fees or placement agent's fees. These types of fees are typically higher for small companies like us. Payment of fees of this type reduces the amount of cash that we receive from a financing transaction and makes it more difficult for us to obtain the amount of financing that need to maintain and expand our operations.

It is our general policy to retain any earnings for use in our operation.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, for use in our business and therefore do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Our stock price is below \$5.00 per share and is treated as a "Penny Stock" which places restrictions on broker-dealers recommending the stock for purchase.

Our common stock is defined as "penny stock" under the Exchange Act and its rules. The SEC has adopted regulations that define "penny stock" to include common stock that has a market price of less than \$5.00 per share, subject to certain exceptions. These rules include the following requirements:

- o broker-dealers must deliver, prior to the transaction a

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disclosure schedule prepared by the SEC relating to the penny stock market;

- o broker-dealers must disclose the commissions payable to the broker-dealer and its registered representative;
- o broker-dealers must disclose current quotations for the securities;
- o if a broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealers presumed control over the market; and
- o a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all penny stocks held in the customer's account and information on the limited market in penny stocks.

Additional sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. If our common stock remains subject to these penny stock rules these disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a shareholder's ability to sell their shares.

Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 8A. Controls and Procedures

- (a) Evaluation of Disclosure Controls and Procedures. Our chief executive officer and chief financial officer have evaluated the effectiveness

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of the design and operation of our "disclosure controls and procedures" (as that term is defined in Rule 13a-14(c) under the Exchange Act) as of the last day of the period covered by this Annual Report on Form 10-KSB. Based on that evaluation, the chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective.

- (b) Changes in Internal Controls. There was no change in our internal control over financial reporting identified in connection with the evaluation during our fourth fiscal quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part III

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act.

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Except as set forth below, the information called for by this item with respect to our executive officers as of March 30, 2005 is furnished in Part I of this report under the heading "Personnel--Executive Officers." The information called for by this item, to the extent it relates to our directors or to certain filing obligations of our directors and executive officers under the federal securities laws, is incorporated herein by reference to the Proxy Statement for our Annual Meeting of Stockholders to be held on May 19, 2005, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

Audit Committee Financial Expert

We do not currently have an "audit committee financial expert," as defined under the rules of the SEC. Because the board of directors consists of only four members and our operations remain amenable to oversight by a limited number of directors, the board has not delegated any of its functions to committees. The entire board of directors acts as our audit committee as permitted under Section 3(a)(58)(B) of the Exchange Act. We believe that all of the members of our board are qualified to serve as the committee and have the experience and knowledge to perform the duties required of the committee. We do not have any independent directors who would qualify as an audit committee financial expert, as defined. We believe that it has been, and may continue to be, impractical to recruit such a director unless and until we are significantly larger.

Code of Ethics

We have not adopted a formal Code of Ethics. Since our company only has four employees, we expect those employees to adhere to high standards of ethics without the need for a formal policy.

Item 10. Executive Compensation.

The information called for by this item is incorporated herein by reference to the Proxy Statement for our Annual Meeting of Stockholders to be held on May 19, 2005, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information called for by this item is incorporated herein by reference to the Proxy Statement for our Annual Meeting of Stockholders to be held on May 19, 2005, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

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Item 12. Certain Relationships and Related Transactions.

The information called for by this item is incorporated herein by reference to the Proxy Statement for our Annual Meeting of Stockholders to be held on May 19, 2005, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

Item 13. Exhibits

Exhibits required by Item 601 of Regulation S-B are incorporated herein by reference and are listed on the attached Exhibit Index, which begins on page X-1 of this Annual Report on Form 10-KSB.

Item 14. Principal Accountant Fees and Services.

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The information called for by this item is incorporated herein by reference to the Proxy Statement for our Annual Meeting of Stockholders to be held on May 19, 2005, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

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Signatures

In accordance with Section 13 or 15(d) of the Exchange Act, the Registrant caused this annual report on Form 10-KSB for the year ended December 31, 2004 to be signed on its behalf by the undersigned, thereunto duly authorized.

Provectus Pharmaceuticals, Inc.

By: /s/ H. Craig Dees

H. Craig Dees, Ph.D. Chief Executive Officer

Date: March 30, 2005

| Signature ----- | Title ----- | |
|--|--|----|
| /s/ H. Craig Dees ----- H. Craig Dees, Ph.D. | Chief Executive Officer (principal executive officer) and Chairman of the Board | Ma |
| /s/ Peter R. Culpepper ----- Peter R. Culpepper, CPA | Chief Financial Officer (principal financial officer and principal accounting officer) | Ma |
| /s/ Timothy C. Scott ----- Timothy C. Scott, Ph.D. | President and Director | Ma |
| /s/ Eric A. Wachter ----- Eric A. Wachter, Ph.D. | Vice President - Pharmaceuticals and Director | Ma |
| /s/ Stuart Fuchs ----- Stuart Fuchs | Director | Ma |

Report of Independent Registered Public Accounting Firm

Board of Directors
Provectus Pharmaceuticals, Inc.
Knoxville, Tennessee

We have audited the accompanying consolidated balance sheets of Provectus Pharmaceuticals, Inc., a development stage company as of December 31, 2004 and 2003 and the related consolidated statements of operations, stockholders' equity, and cash flows for the period from January 17, 2002 (inception) to December 31, 2004 and for each of the two years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Provectus Pharmaceuticals, Inc. at December 31, 2004 and 2003, and the results of its operations and its cash flows for the period from January 17, 2002 (inception) to December 31, 2004 and for each of the two years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

/s/BDO Seidman, LLP

Chicago, Illinois
February 11, 2005

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Provectus Pharmaceuticals, Inc.
(A Development-Stage Company)

CONSOLIDATED BALANCE SHEETS

December 31,
2004

| | | |
|--|----|--------------|
| ----- | | |
| Assets | | |
| Current Assets | | |
| Cash | \$ | 10,774 |
| Stock subscription receivable | | - |
| Inventory | | 94,142 |
| Prepaid expenses and other current assets | | 20,582 |
| Prepaid consulting expense | | 205,427 |
| Prepaid commitment fee, net of amortization of \$38,326 | | 272,540 |
| ----- | | |
| Total Current Assets | | 603,465 |
| ----- | | |
| Equipment and Furnishings, less accumulated depreciation of \$366,571 and \$244,760 | | - |
| Patents, net of amortization of \$1,420,537 and \$749,417 | | 10,294,908 |
| Deferred loan costs, net of amortization of \$35,922 and \$19,569 | | 270,578 |
| Other Assets | | 27,000 |
| ----- | | |
| | \$ | 11,195,951 |
| ----- | | |
| Liabilities and Stockholders' Equity | | |
| Current Liabilities | | |
| Accounts payable - trade | \$ | 154,214 |
| Accrued compensation | | 156,377 |
| Accrued expenses | | 6,240 |
| Accrued interest | | 43,670 |
| Short-term convertible debt, net of debt discount of \$-0- and \$442,623 | | - |
| Gryffindor convertible debt, net of debt discount of \$95,157 and \$57,052 | | 1,090,802 |
| ----- | | |
| Total Current Liabilities | | 1,451,303 |
| ----- | | |
| Loan From Stockholder | | 149,000 |
| ----- | | |
| Cornell convertible debt, net of debt discount of \$316,053 and \$-0- | | 433,947 |
| ----- | | |
| Stockholders' Equity | | |
| Common stock; par value \$.001 per share; 100,000,000 shares authorized; 16,133,876 and 10,867,509 shares issued and outstanding, respectively | | 16,134 |
| Paid-in capital | | 23,711,540 |
| Deficit accumulated during the development stage | | (14,565,973) |
| ----- | | |

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| | |
|----------------------------|------------------|
| Total Stockholders' Equity | 9,161,701 |
| | ----- |
| | \$ 11,195,951 \$ |
| | ----- |

See accompanying notes to financial statements.

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CONSOLIDATED STATEMENTS OF OPERATIONS

| | Year Ended December 31, 2004 | Year Ended December 31, 2003 |
|---|------------------------------------|------------------------------------|
| | ----- | ----- |
| Revenues | | |
| OTC Product Revenue | \$ 18,728 | \$ - |
| Medical Device Revenue | 13,125 | - |
| | ----- | ----- |
| Total revenues | 31,853 | - |
| Cost of Sales | 10,781 | - |
| | ----- | ----- |
| Gross Profit | 21,072 | - |
| Operating Expenses | | |
| Research and development | 1,291,817 | 724,924 |
| General and administrative | 1,690,841 | 1,582,250 |
| Amortization | 671,120 | 671,120 |
| | ----- | ----- |
| Total operating loss | (3,632,706) | (2,978,294) |
| Gain on sale of equipment | - | 55,000 |
| Net loss on extinguishment of debt | (101,412) | - |
| Interest expense | (610,407) | (232,019) |
| | ----- | ----- |
| Net Loss Applicable to Common Stockholders | \$ (4,344,525) | \$ (3,155,313) |
| | ----- | ----- |
| Basic and Diluted Loss Per Common Share | (0.31) | (0.33) |
| | ----- | ----- |
| Weighted Average Number of Common Shares Outstanding - Basic and Diluted | 14,122,559 | 9,706,064 |

See accompanying notes to financial statements.

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CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| | Common Stock | | |
|--|---------------------|-----------|--------------------|
| | Number of Shares | Par Value | Paid-in Capital |
| Balance, at January 17, 2002 | - | \$ - | \$ - |
| Issuance to founding shareholders | 6,000,000 | 6,000 | (6,000) |
| Sale of stock | 50,000 | 50 | 24,950 |
| Issuance of stock to employees | 510,000 | 510 | 931,490 |
| Issuance of stock for services | 120,000 | 120 | 359,880 |
| Net loss for the period from January 17, 2002 (inception) to April 23, 2002 (date of reverse merger) | - | - | - |
| Balance, at April 23, 2002 | 6,680,000 | 6,680 | 1,310,320 |
| Shares issued in reverse merger | 265,763 | 266 | (3,911) |
| Issuance of stock for services | 1,900,000 | 1,900 | 5,142,100 |
| Purchase and retirement of stock | (400,000) | (400) | (47,600) |
| Stock issued for acquisition of Valley Pharmaceuticals | 500,007 | 500 | 12,225,820 |
| Exercise of warrants | 452,919 | 453 | - |
| Warrants issued in connection with convertible debt | - | - | 126,587 |
| Stock and warrants issued for acquisition of Pure-ific | 25,000 | 25 | 26,975 |
| Net loss for the period from April 23, 2002 (date of reverse merger) to December 31, 2002 | - | - | - |
| Balance, at December 31, 2002 | 9,423,689 | 9,424 | 18,780,291 |
| Issuance of stock for services | 764,000 | 764 | 239,036 |
| Issuance of warrants for services | - | - | 145,479 |
| Stock to be issued for services | - | - | 281,500 |
| Employee compensation from stock options | - | - | 34,659 |
| Issuance of stock pursuant to Regulation S | 679,820 | 680 | 379,667 |
| Beneficial conversion related to convertible debt | - | - | 601,000 |
| Net loss for the year ended December 31, 2003 | - | - | - |

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| | | | | | | | |
|---|------------|----|--------|----|------------|----|---|
| Balance, at December 31, 2003 | 10,867,509 | \$ | 10,868 | \$ | 20,461,632 | \$ | (|
| Issuance of stock for services | 733,872 | | 734 | | 449,190 | | |
| Issuance of warrants for services | - | | - | | 495,480 | | |
| Exercise of warrants | 132,608 | | 133 | | 4,867 | | |
| Employee compensation from stock options | - | | - | | 15,612 | | |
| Issuance of stock pursuant to Regulation S | 2,469,723 | | 2,469 | | 790,668 | | |
| Issuance of stock pursuant to Regulation D | 1,930,164 | | 1,930 | | 1,286,930 | | |
| Beneficial conversion related to convertible debt | - | | - | | 360,256 | | |
| Issuance of convertible debt with warrants | - | | - | | 105,250 | | |
| Repurchase of beneficial conversion feature | - | | - | | (258,345) | | |
| Net loss for the year ended December 31, 2004 | - | | - | | - | | |
| Balance, at December 31, 2004 | 16,133,876 | \$ | 16,134 | \$ | 23,711,540 | \$ | |

See accompanying notes to financial statements.

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PROVECTUS PHARMACEUTICALS, INC.
(A Development-Stage Company)
CONSOLIDATED STATEMENTS OF CASH FLOW

| | | Year Ended December 31, 2004 | Year Ended December 31, 2003 |
|--|----|------------------------------------|------------------------------------|
| Cash Flows From Operating Activities | | | |
| Net loss | \$ | (4,344,525) | \$ (3,155,3 |
| Adjustments to reconcile net loss to net cash used in operating activities | | | |
| Depreciation | | 121,811 | 228,3 |
| Amortization of patents | | 671,120 | 671,1 |
| Amortization of original issue discount | | 360,663 | 120,6 |
| Amortization of commitment fee | | 38,326 | |
| Amortization of prepaid consultant expense | | 606,888 | 245,9 |
| Amortization of deferred loan costs | | 120,953 | 19,5 |
| Loss on extinguishment of debt | | 101,412 | |
| Compensation through issuance of stock options | | 15,612 | 34,6 |
| Compensation through issuance of stock | | - | |
| Issuance of stock for services | | 76,558 | |
| Issuance of warrants for services | | 22,481 | |
| Gain on sale of fixed asset | | - | (55,0 |
| Increase (decrease) in assets | | | |
| Prepaid expenses | | 5,645 | 9,2 |
| Inventory | | (21,564) | (72,5 |
| Increase (decrease) in liabilities | | | |
| Accounts payable | | 53,574 | 1,7 |

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| | | |
|---|-------------|----------|
| Accrued expenses | (143,783) | 432,2 |
| ----- | | |
| Net cash used in operating activities | (2,314,829) | (1,519,2 |
| ----- | | |
| Cash Flows From Investing Activities | | |
| Proceeds from sale of fixed asset | - | 180,0 |
| Capital expenditures | (396) | (3,3 |
| ----- | | |
| Net cash (used in) provided by investing activities | (396) | 176,6 |
| ----- | | |
| Cash Flows From Financing Activities | | |
| Proceeds from loans from stockholder | - | 40,0 |
| Proceeds from convertible debt | 750,000 | 525,9 |
| Proceeds from sale of common stock | 2,169,873 | 292,4 |
| Proceeds from exercise of warrants | 5,000 | |
| Cash paid to retire convertible debt | (500,000) | |
| Cash paid for deferred loan costs | (162,500) | (69,5 |
| Premium paid on extinguishment of debt | (100,519) | |
| Purchase and retirement of common stock | - | |
| ----- | | |
| Net cash provided by financing activities | 2,161,854 | 788,9 |
| ----- | | |

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| | Year Ended December 31, 2004 | Year Ended December 31, 2003 | |
|------------------------------|------------------------------------|------------------------------------|----|
| ----- | | | |
| Net Change in Cash | \$ (153,371) | \$ (553,688) | \$ |
| Cash, at beginning of period | \$ 164,145 | \$ 717,833 | \$ |
| ----- | | | |
| Cash, at end of period | \$ 10,774 | \$ 164,145 | \$ |
| ----- | | | |

Supplemental Disclosure of Noncash Investing and Financing Activities

December 31, 2004
 Issuance of stock for prepaid services
of \$62,499
 Issuance of warrants for prepaid services
of \$329,000
 Issuance of stock in exchange for
standby equity commitment of \$310,866
 Discount on convertible debt with warrants
of \$105,250
 Deferred loan costs through the issuance

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of warrants of \$144,000
Beneficial conversion on convertible debt
of \$360,256
Conversion of accrued interest of \$160,000
to convertible debt

December 31, 2003

Issuance or commitment to issue stock and
warrants for prepaid services of \$666,779
Stock subscription receivable recorded of
\$87,875
Discount on convertible debt with warrants
of \$500,000
Deferred loan costs through the issuance
of warrants of \$101,000

See accompanying notes to financial statement.

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Provectus Pharmaceuticals, Inc.
(A Development Stage Company)

Notes to Consolidated Financial Statements

1. Organization and Significant Accounting Policies

Nature of Operations

Provectus Pharmaceuticals, Inc. (together with its subsidiaries, the "Company") is a development-stage biopharmaceutical company that is focusing on developing minimally invasive products for the treatment of psoriasis and other topical diseases, cancer, and certain laser device technology. Through a previous acquisition, the Company also intends to develop, manufacture, and distribute over-the-counter pharmaceuticals. To date the Company has no material revenues.

Principles of Consolidation

Intercompany balances and transactions have been eliminated in consolidation.

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Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the

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financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Inventory

Inventory, consisting principally of finished goods, is stated at the lower of cost or market. Cost is determined using a first-in, first-out method.

Deferred Loan Costs and Debt Discounts

The costs related to the issuance of the convertible debt, including lender fees, legal fees, due diligence costs, escrow agent fees and commissions, have been recorded as deferred loan costs and are being amortized over the term of the loan using the effective interest method. Additionally, the Company recorded debt discounts related to warrants and beneficial conversion features issued in connection with the debt. Debt discounts are being amortized over the term of the loan using the effective interest method.

Equipment and Furnishings

Equipment and furnishings acquired through the acquisition of Valley Pharmaceuticals, Inc. (Note 2) have been stated at carry over basis. Other equipment and furnishings are stated at cost. Depreciation of equipment is provided for using the straight-line method over the estimated useful lives of the assets. Computers and laboratory equipment are being depreciated over five years, furniture and fixtures are being depreciated over seven years.

Long-Lived Assets

The Company reviews the carrying values of its long-lived assets for possible impairment whenever an event or change in circumstances indicates that the carrying amount of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair value less cost to sell.

Patent Costs

Internal patent costs are expensed in the period incurred. Patents purchased are capitalized and amortized over the remaining life of the patent.

Patents at December 31, 2004 were acquired as a result of the merger with Valley Pharmaceuticals, Inc. ("Valley") (Note 2). The majority shareholders of Provectus also owned all of the shares of Valley and therefore the assets acquired from Valley were recorded at their carry over basis. The patents are being amortized over the remaining lives of the patents, which range from 12-16 years. Annual amortization of the patents is expected to be approximately \$671,000 per year for the next five years.

Research and Development

Research and development costs are charged to expense when incurred. An allocation of payroll expenses was made based on a percentage estimate of time spent. The research and development costs include the following: consulting - IT, depreciation, lab equipment repair, lab supplies, insurance, legal - patents, office supplies, payroll expenses, rental - building, repairs, software, taxes and fees, and utilities.

Income Taxes

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The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the tax basis and financial reporting basis of certain assets and liabilities based upon currently enacted tax rates expected to be in effect when such amounts are realized or settled.

Since inception of the Company on January 17, 2002, the Company has generated tax net operating losses of approximately \$5.9 million, expiring in 2022 through 2024. The Company has not recorded an income tax benefit for the net operating losses as the Company is in the development stage and realization of the losses is not considered more likely than not. An income tax valuation allowance has been provided for the losses realized to date.

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The amortization of patents, noncash stock compensation and the amortization of debt discounts related to beneficial conversions are not deductible for tax purposes. In addition, the Company may have acquired certain net operating losses in its acquisition of Valley Pharmaceuticals, Inc. (Note 2). However, the amount of these net operating losses has not been determined and even if recorded the amount would be fully reserved.

Basic and Diluted Loss Per Common Share

Basic and diluted loss per common share and diluted loss per common share is computed based on the weighted Per Common Share average number of common shares outstanding. Loss per share excludes the impact of outstanding options, warrants, and convertible debt as they are antidilutive. Potential common shares excluded from the calculation at December 31, 2004 are 1,725,000 options, 4,092,393 warrants and 3,176,368 shares issuable upon the conversion of convertible debt and accrued interest. Additionally, the Company is committed to issue 10,000 warrants.

Financial Instruments

The carrying amounts reported in the consolidated balance sheets for cash, accounts payable and accrued expenses approximate fair value because of the short-term nature of these amounts. The Company believes the fair value of its fixed-rate borrowings approximates the market value.

Stock Based Compensation

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock Based Compensation" (SFAS No. 123), but applies the intrinsic value method where compensation expense, if any, is recorded as the difference between the exercise price and the market price, as set forth in Accounting Principles Board Opinion No. 25 for stock options granted to employees and directors. Options granted to non-employees are accounted for under SAS 123. SAS 123 requires options to be accounted for based on their fair value.

In 2003, the Company issued stock options to employees in which the exercise price was less than the market price on the date of grant. These options vest over three years and accordingly, \$15,612 and \$34,659 of expense was recorded for the year ended December 31, 2004 and 2003, respectively.

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For stock options granted to employees during 2004 and 2003, the Company has estimated the fair value of each option granted using the Black-Scholes option pricing model with the following assumptions:

| | 2004 | 2003 |
|---|---------|----------|
| Weighted average fair value per options granted | \$ 1.10 | \$ 0.60* |
| Significant assumptions (weighted average) | | |
| Risk-free interest rate at grant date | 2.0% | 2.0% |
| Expected stock price volatility | 150% | 150% |
| Expected option life (years) | 10 | 10 |

* The weighted average fair value for both the options less than market price at date of grant and options equal to market price at date of grant was \$0.60.

If the Company had elected to recognize compensation expense based on the fair value at the grant dates, consistent with the method prescribed by SFAS No. 123, net loss per share would have been changed to the pro forma amount indicated below:

| | Year Ended December 31, 2004 | Year Ended December 31, 2003 |
|--|------------------------------------|------------------------------------|
| Net loss, as reported | \$ (4,344,525) | \$ (3,155,313) |
| Add stock-based employee compensation expense included in reported net loss | 15,612 | 34,659 |
| Less total stock-based employee compensation expense determined under the fair value based method for all awards | (698,125) | (132,663) |
| Pro forma net loss | \$ (5,027,038) | \$ (3,253,317) |
| Basic and diluted loss per common share, as reported | \$ (0.31) | \$ (0.33) |
| Basic and diluted loss per common share, pro forma | \$ (0.36) | \$ (0.34) |

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Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), "Share-Based Payment," which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends SFAS No. 95, "Statement of Cash Flows." Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. This revised standard

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will be effective for us beginning with the third quarter in 2005.

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB 25 intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of SFAS No. 123(R)'s fair value method will have an impact on the result of operations, although it will have no impact on the overall financial position. The impact of the modified prospective adoption of SFAS No. 123(R) cannot be estimated at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net income and earnings per share.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs: an amendment of ARB No. 43, Chapter 4," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and waster material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not believe the provisions of SFAS No. 151, when applied, will have a material impact on the financial position or results of operations.

Revenue Recognition

The Company recognizes revenue when product is shipped. When advance payments are received, these payments are recorded as deferred revenue and recognized when the product is shipped.

Reclassifications

Certain 2003 amounts have been reclassified to conform to the 2004 presentation.

2. Recapitalization and Merger.

On April 23, 2002, Provectus Pharmaceutical, Inc., a Nevada corporation and a Merger "blank check" public company, acquired Provectus Pharmaceuticals, Inc., a privately held Tennessee corporation ("PPI"), by issuing 6,680,000 shares of common stock of Provectus Pharmaceutical to the stockholders of PPI in exchange for all of the issued and outstanding shares of PPI, as a result of which Provectus Pharmaceutical changed its name to Provectus Pharmaceuticals, Inc. (the "Company") and PPI became a wholly owned subsidiary of the Company. Prior to the transaction, PPI had no significant operations and had not generated any revenues.

For financial reporting purposes, the transaction has been reflected in the accompanying financial statements as a recapitalization of PPI and the financial statements reflect the historical financial information of PPI which was incorporated on January 17, 2002. Therefore, for accounting purposes, the shares recorded as issued in the reverse merger are the 265,763 shares owned by Provectus Pharmaceuticals, Inc. shareholders prior to the reverse merger.

The issuance of 6,680,000 shares of common stock of Provectus Pharmaceutical, Inc. to the stockholders of PPI in exchange for all of the issued and outstanding shares of PPI was done in anticipation of PPI acquiring Valley Pharmaceuticals, Inc, which owned the intellectual property to be used in the Company's operations.

On November 19, 2002, the Company acquired Valley Pharmeceuticals, Inc,

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("Valley") a privately-held Tennessee corporation by merging PPI with and into Valley and naming the surviving company Xantech Pharmaceuticals, Inc. Valley had no significant operations and had not generated any revenues. Valley was formed to hold certain intangible assets which were transferred from an entity which was majority owned by the shareholders of Valley. Those shareholders gave up their shares of the other company in exchange for the intangible assets in a non-pro rata split off. The intangible assets were valued based on the market price of the stock given up in the split-off. The shareholders of Valley also owned the majority of the shares of the Company at the time of the transaction. The Company issued 500,007 shares of stock in exchange for the net assets of Valley which were valued at \$12,226,320 and included patents of \$11,715,445 and equipment and furnishings of \$510,875.

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3. Equity Transactions

- (a) During 2002, the Company issued 2,020,000 shares of stock in exchange for consulting services. These services were valued based on the fair market value of the stock exchanged which resulted in consulting costs charged to operations of \$5,504,000.
- (b) During 2002, the Company issued 510,000 shares of stock to employees in exchange for services rendered. These services were valued based on the fair market value of the stock exchanged which resulted in compensation costs charged to operations of \$932,000.
- (c) In February 2002, the Company sold 50,000 shares of stock to a related party in exchange for proceeds of \$25,000.
- (d) In June 2002, the Company issued a warrant to a consultant for the purchase of 100,000 shares at \$2.29 per share. The warrant is only exercisable upon the successful introduction of the Company to a designated pharmaceutical company. The warrant was forfeited in 2004.
- (e) In October 2002, the Company purchased 400,000 outstanding shares of stock from one shareholder for \$48,000. These shares were then retired.
- (f) On December 5, 2002, the Company purchased the assets of Pure-ific L.L.C, a Utah limited liability company, and created a wholly owned subsidiary called Pure-ific Corporation, to operate the Pure-ific business which consists of product formulations for Pure-ific personal sanitizing sprays, along with the Pure-ific trademarks. The assets of Pure-ific were acquired through the issuance of 25,000 shares of the Company's stock with a fair market value of \$0.50 and the issuance of various warrants. These warrants included warrants to purchase 10,000 shares of the Company's stock at an exercise price of \$0.50 issuable on the first, second and third anniversary dates of the acquisition. Accordingly, the fair market value of these warrants of \$14,500, determined using the Black-Scholes option pricing model, was recorded as additional purchase price for the acquisition of the Pure-ific assets. In 2004, 20,000 warrants were issued for the first and second anniversary dates. 10,000 of these warrants were exercised in 2004. In addition, warrants to purchase 80,000 shares of stock at an exercise price of \$0.50 will be issued upon the achievement of certain sales targets of the Pure-ific product. At December 31, 2004 and 2003, none of these targets have been met and accordingly, no costs have been

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recorded.

- (g) In 2003, the Company issued 764,000 shares to consultants in exchange for services rendered, consisting of 29,000 shares issued in January valued at \$11,600, 35,000 shares issued in March valued at \$11,200, and 700,000 shares issued in October valued at \$217,000. The value for these shares was based on the market value of the shares issued. As all of these amounts represented payments for services to be provided in the future and the shares were fully vested and non-forfeitable, a prepaid consulting expense was recorded in 2003 of which \$0 and \$144,667 remained as of December 31, 2004 and 2003, respectively. Consulting costs charged to operations were \$144,667 in 2004 and \$95,133 in 2003.
- (h) In November and December 2003, the Company committed to issue 341,606 shares to consultants in exchange for services rendered. The total value for these shares was \$281,500 which was based on the market value of the shares issued. The shares were issued in January 2004. As these amounts represented payments for services to be provided in the future and the shares were fully vested and non-forfeitable, a prepaid consulting expense was recorded in 2003 of which \$0 and \$231,983 remained as of December 31, 2004 and 2003, respectively. Consulting costs charged to operations were \$231,983 in 2004 and \$49,517 in 2003.

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- (i) The Company applies the recognition provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," in accounting for stock options and warrants issued to nonemployees. In January 2003, the Company issued 25,000 warrants to a consultant for services rendered. In February 2003, the Company issued 360,000 warrants to a consultant, 180,000 of which were fully vested and non-forfeitable at the issuance and 180,000 of which were cancelled in August 2003 due to the termination of the consulting contract. In September 2003, the Company issued 200,000 warrants to two consultants in exchange for services rendered. In November 2003, the Company issued 100,000 warrants to one consultant in exchange for services rendered. As the fair market value of these services was not readily determinable, these services were valued based on the fair market value, determined using the Black-Scholes option-pricing model. Fair market value for the warrants issued in 2003 ranged from \$0.20 to \$0.24 and totalled \$145,479.. As these amounts represented payments for services to be provided in the future and the warrants were fully vested and non-forfeitable, a prepaid consulting expense was recorded in 2003 of which \$0 and \$44,167 remained as of December 31, 2004 and 2003, respectively. Consulting costs charged to operations were \$44,167 in 2004 and \$101,312 in 2003.

In May 2004, the Company issued 20,000 warrants to consultants in exchange for services rendered. Consulting costs charged to operations were \$18,800. In August 2004, the Company issued 350,000 warrants to consultants in exchange for services valued at \$329,000. At December 31, 2004, \$123,375 of these costs have been charged to operations with the remaining \$205,427 recorded as prepaid consulting expense as it represents payments for future services and the warrants are fully-vested and non-forfeitable. In December 2004, the Company issued 10,000 warrants to consultants in exchange for services valued at \$3,680. Fair market value for the warrants issued in 2004 ranged from \$0.37 to \$0.94.

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(j) In December 2003, the Company commenced an offering for sale of restricted common stock. As of December 31, 2003, the Company had sold 874,871 shares at an average gross price of \$1.18 per share. As of December 31, 2003, the Company had received net proceeds of \$292,472 and recorded a stock subscription receivable of \$87,875 for stock subscriptions prior to December 31, 2003 for which payment was received subsequent to December 31, 2003. The transaction is a Regulation S offering to foreign investors as defined by Regulation S of the Securities Act. The restricted shares cannot be traded for 12 months. After the first 12 months, sales of the shares are subject to restrictions under rule 144 for an additional year. The Company has engaged a placement agent to assist the offering. Costs related to the placement agent of \$651,771 have been off-set against the gross proceeds of \$1,032,118 and therefore are reflected as a direct reduction of equity at December 31, 2003. At December 31, 2003, 195,051 shares had not yet been issued. These shares were issued in the first quarter of 2004.

In 2004, the Company sold 2,274,672 shares of restricted common stock under this offering of which 1,672,439 shares were issued in the first quarter 2004 and 602,233 were issued in the second quarter 2004. Shares were sold during 2004 at an average gross price of \$1.05 per share with net proceeds of \$793,137. Costs related to the placement agent for proceeds received in 2004 of \$1,588,627 have been off-set against gross proceeds of \$2,381,764.

(k) In January 2004, the Company issued 10,000 shares to a consultant in exchange for services rendered. Consulting costs charged to operations were \$11,500. In March 2004, the Company committed to issue 36,764 shares to consultants in exchange for services. These shares were recorded as a prepaid consulting expense and were fully amortized at December 31, 2004. Consulting costs charged to operations were \$62,500. These 36,764 shares, along with 75,000 shares committed in 2003 were issued in August 2004. The 75,000 shares committed to be issued in 2003 were the result of a cashless exercise of 200,000 warrants in 2003, which were not issued as of December 31, 2003. In August 2004, the Company also issued 15,000 shares to a consultant in exchange for services rendered. Consulting costs charged to operations were \$25,200. In September 2004, the Company issued 16,666 shares to a consultant in exchange for services rendered. Consulting costs charged to operations were \$11,666. In October 2004, the Company issued 16,666 shares to a consultant in exchange for services rendered. Consulting costs charged to operations were \$13,666. In November 2004, the Company issued 16,666 shares to a consultant in exchange for services rendered. Consulting costs charged to operations were \$11,000. In December 2004, the Company issued 7,500 shares to a consultant in exchange for services rendered. Consulting costs charged to operations were \$3,525.

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- (1) On June 25, 2004, the Company entered into an agreement to sell 1,333,333 shares of common stock at a purchase price of \$.75 per share for an aggregate purchase price of \$1,000,000. Payments were received in four installments, the last of which was on August 9, 2004. Stock issuance costs included 66,665 shares of stock valued at \$86,666 and cash costs of \$69,000. The cash costs have been off-set against the proceeds received. In conjunction with the sale of the common stock, the Company issued 1,333,333 warrants with an exercise price of \$1.00 and a termination date of three years from the installment payment dates. In addition, the Company has given the

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investors an option to purchase 1,333,333 shares of additional stock including the attachment of warrants under the same terms as the original agreement. This option expired February 8, 2005.

- (m) Pursuant to a Standby Equity Distribution Agreement ("SEDA") dated July 28, 2004 between the Company and Cornell Capital Partners, L.P. ("Cornell"), the Company may, at its discretion, issue shares of common stock to Cornell at any time until June 28, 2006. As of December 31, 2004 there were no shares issued pursuant to the SEDA. The facility is subject to having in effect a registration statement covering the shares. A registration statement covering 2,023,552 shares was declared effective by the Securities and Exchange Commission on November 16, 2004. The maximum aggregate amount of the equity placements pursuant to the SEDA is \$20 million, and the Company may draw down up to \$1 million per month. Pursuant to the SEDA, on July 28, 2004, the Company issued 190,084 shares of common stock to Cornell and 7,920 shares of common stock to Newbridge Securities Corporation as commitment shares. These 198,004 shares had a FMV of \$310,866 on July 28, 2004 which is being amortized over the term of the commitment period which is one year from the date of registration. At December 31, 2004, \$38,326 has been amortized.
- (n) On November 16, 2004, the Company completed a private placement transaction with 14 accredited investors, pursuant to which the Company sold 530,166 shares of common stock at a purchase price of \$0.75 per share, for an aggregate purchase price of \$397,625. In connection with the sale of the common stock, the Company also issued warrants to the investors to purchase up to 795,249 shares of our common stock at an exercise price of \$1.00 per share. The Company paid \$39,764 and issued 198,812 warrants to Venture Catalyst, LLC as placement agent for this transaction. The cash costs have been off-set against the proceeds received

4. Stock Incentive Plan

The Company maintains one long-term incentive compensation plan, the Provectus Pharmaceuticals, Inc. 2002 Stock Plan, which provides for the issuance of up to 3,000,000 shares of common stock pursuant to stock options, stock appreciation rights, stock purchase rights and long-term performance awards granted to key employees and directors of and consultants to the Company.

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Options granted under the 2002 Stock Plan may be either "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code or options which are not incentive stock options. The stock options are exercisable over a period determined by the Board of Directors (through its Compensation Committee), but generally no longer than 10 years after the date they are granted.

On March 1, 2004, the Company issued 1,200,000 stock options to employees. The options vest over three years with 225,000 options vesting on the date of grant. The exercise price is the fair market price on the date of issuance, and all options were outstanding at December 31, 2004.

On May 27, 2004, the Company issued 100,000 stock options to the Board of Directors. The options vested immediately on the date of grant. The exercise price is the fair market price on the date of issuance, and all options were outstanding at December 31, 2004.

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On June 28, 2004, the Company issued 100,000 stock options to an employee. The options vest over four years with 25,000 options vesting on the date of grant. The exercise price is the fair market price on the date of issuance, and all options were outstanding at December 31, 2004.

The following table summarizes the options granted, exercised and outstanding as of December 31, 2003 and 2004, respectively. There were no options issued in 2002.

| | Shares | Exercise Price Per Share |
|---|-----------|--------------------------|
| | ----- | ----- |
| Outstanding at January 1, 2003 | - | - |
| Granted * | 452,000 | \$0.26 - \$0.60 |
| Exercised | - | - |
| Forfeited | (95,750) | \$0.26 - \$0.32 |
| | ----- | ----- |
| Outstanding at December 31, 2003 | 356,250 | \$0.26 - \$0.60 |
| | ===== | ===== |
| Options exercisable at December 31, 2003 | 187,500 | \$0.26 - \$0.60 |
| | ===== | ===== |
| Outstanding at January 1, 2004 | 356,250 | \$0.26 - \$0.60 |
| Granted | 1,400,000 | \$0.95 - \$1.25 |
| Exercised | - | - |
| Forfeited | (31,250) | \$0.26 - \$0.32 |
| | ----- | ----- |
| Outstanding at December 31, 2004 | 1,725,000 | \$0.32 - \$1.25 |
| | ===== | ===== |
| Options exercisable at December 31, 2004 | 562,500 | \$0.32 - \$1.25 |
| | ===== | ===== |

* Includes 352,000 options granted at less than market price with a weighted average exercise price of \$0.31 and 100,000 options granted at a price equal to market price with a weighted average exercise price of \$0.60.

The following table summarizes information about stock options outstanding at December 31, 2004.

| | Options Outstanding | | | Options Exercisable | | |
|--------|---------------------|---|---|---------------------------------|---|---------------------------------|
| | Exercise Price | Number Outstanding at December 31, 2004 | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number Exercisable at December 31, 2004 | Weighted Average Exercise Price |
| | ----- | ----- | ----- | ----- | ----- | ----- |
| \$0.32 | 225,000 | 8.58 years | 0.32 | 112,500 | 0.32 | |
| \$0.60 | 100,000 | 8.58 years | 0.60 | 100,000 | 0.60 | |
| \$1.10 | 1,200,000 | 9.17 years | 1.10 | 225,000 | 1.10 | |
| \$0.95 | 100,000 | 9.42 years | 0.95 | 100,000 | 0.95 | |
| \$1.25 | 100,000 | 9.50 years | 1.25 | 25,000 | 1.25 | |
| | ----- | ----- | ----- | ----- | ----- | |
| | 1,725,000 | 9.00 years | \$0.97 | 562,500 | \$0.84 | |

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The following table summarizes the warrants granted, exercised and outstanding as of December 31, 2003 and 2004, respectively.

| | Warrants | Exercise Price Per Warrant | Weighted Average Exercise Price |
|--|-----------|----------------------------------|--|
| | ----- | ----- | ----- |
| Outstanding at January 1, 2003 | 100,000 | \$2.29 | \$ |
| Granted | 1,285,000 | \$0.25 - \$1.25 | \$ |
| Exercised | (200,000) | \$0.75 | \$ |
| Forfeited | (180,000) | \$0.25 - \$0.50 | \$ |
| | ----- | ----- | ----- |
| Outstanding at December 31, 2003 | 1,005,000 | \$0.25 - \$2.29 | \$ |
| | ===== | ===== | ===== |
| Warrants exercisable at December 31, 2003 | 905,000 | \$0.25 - \$1.25 | \$ |
| | ===== | ===== | ===== |
| Outstanding at January 1, 2004 | 1,005,000 | \$0.25 - \$2.29 | \$ |
| Granted | 3,402,393 | \$0.50 - \$1.00 | \$ |
| Exercised | (190,000) | \$0.25 - \$0.50 | \$ |
| Forfeited | (125,000) | \$0.75 - \$2.29 | \$ |
| | ----- | ----- | ----- |
| Outstanding at December 31, 2004 | 4,092,393 | \$0.50 - \$1.25 | \$ |
| | ===== | ===== | ===== |
| Warrants exercisable at December 31, 2004 | 4,092,393 | \$0.50 - \$1.25 | \$ |
| | ===== | ===== | ===== |

Warrants exercised include a cashless exercise of 200,000 warrants in exchange for 75,000 shares in 2003 and a cashless exercise of 180,000 warrants in exchange for 122,608 shares in 2004. At December 31, 2004 there were 10,000 warrants committed but not issued.

The following table summarizes information about warrants outstanding at December 31, 2004.

| | Warrants Outstanding | | | Warrants Exercisable | |
|----------------|--|---|--|--|--|
| | Number Outstanding at December 31, 2004 | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number Exercisable at December 31, 2004 | Weighted Average Exercise Price |
| Exercise Price | ----- | ----- | ----- | ----- | ----- |
| | | | | | |

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| | | | | | |
|--------|-----------|-------|--------|-----------|--------|
| \$0.50 | 10,000 | 1.92 | \$0.50 | 10,000 | \$0.50 |
| \$0.75 | 189,525 | 3.42 | \$0.75 | 189,525 | \$0.75 |
| \$0.94 | 20,000 | 2.25 | \$0.94 | 20,000 | \$0.94 |
| \$1.00 | 3,772,868 | 3.48 | \$1.00 | 3,772,868 | \$1.00 |
| \$1.25 | 100,000 | 1.92 | \$1.25 | 100,000 | \$1.25 |
| ----- | ----- | ----- | ----- | ----- | ----- |
| | 4,092,393 | 3.43 | \$0.99 | 4,092,393 | \$0.99 |
| | ===== | ===== | ===== | ===== | ===== |

5. Convertible Debt.

(a) Pursuant to a Convertible Secured Promissory Note and Warrant Purchase Agreement dated November 26, 2002 (the "Purchase Agreement") between the Company and Gryffindor Capital Partners I, L.L.C., a Delaware limited liability company ("Gryffindor"), Gryffindor purchased the Company's \$1 million Convertible Secured Promissory Note dated November 26, 2002 (the "Note"). The Note bears interest at 8% per annum, payable quarterly in arrears, and is due and payable in

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full on November 26, 2004. Subject to certain exceptions, the Note is convertible into shares of the Company's common stock on or after November 26, 2003, at which time the principal amount of the Note is convertible into common stock at the rate of one share for each \$0.737 of principal so converted and any accrued but unpaid interest on the Note is convertible at the rate of one share for each \$0.55 of accrued but unpaid interest so converted.

The Company's obligations under the Note are secured by a first priority security interest in all of the Company's assets, including the capital stock of the Company's wholly owned subsidiary Xantech Pharmaceuticals, Inc., a Tennessee corporation ("Xantech"). In addition, the Company's obligations to Gryffindor are guaranteed by Xantech, and Xantech's guarantee is secured by a first priority security interest in all of Xantech's assets.

Pursuant to the Purchase Agreement, the Company also issued to Gryffindor and to another individual Common Stock Purchase Warrants dated November 26, 2002 (the "Warrants"), entitling these parties to purchase, in the aggregate, up to 452,919 shares of common stock at a price of \$0.001 per share. Simultaneously with the completion of the transactions described in the Purchase Agreement, the Warrants were exercised in their entirety. The \$1,000,000 in proceeds received in 2002 was allocated between the long-term debt and the warrants on a pro-rata basis. The value of the warrants was determined using a Black-Scholes option pricing model. The allocated fair value of these warrants was \$126,587 and was recorded as a discount on the related debt and is being amortized over the life of the debt using the effective interest method. Amortization of \$57,052 and \$63,292 have been recorded as additional interest expense as of December 31, 2004 and 2003, respectively.

In 2003, an additional \$25,959 was added to the 2002 convertible debt outstanding.

Pursuant to an agreement dated November 26, 2004 between the Company and Gryffindor, the Company issued Gryffindor a Second Amended and Restated Senior Secured Convertible Note dated November 26, 2004 in the amended principal amount of \$1,185,959 which included the original note principal

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plus accrued interest. The second amended note bears interest at 8% per annum, payable quarterly in arrears, is due and payable in full on November 26, 2005, and amends and restates the amended note in its entirety.

Subject to certain exceptions, the Note is convertible into shares of the Company's common stock on or after November 26, 2004, at which time the principal amount of the Note is convertible into common stock at the rate of one share for each \$0.737 of principal so converted and any accrued but unpaid interest on the Note is convertible at the rate of one share for each \$0.55 of accrued but unpaid interest so converted.

The Company issued warrants to Gryffindor to purchase up to 525,000 shares of the Company's common stock at an exercise price of \$1.00 per share in satisfaction of issuing Gryffindor the Second Amended and Restated Senior Secured Convertible Note dated November 26, 2004. The value of these warrants was determined to be \$105,250 using a Black-Scholes option-pricing model and was recorded as a discount on the related debt and is being amortized over the life of the debt using the effective interest method. Amortization of \$10,093 has been recorded as additional interest expense as of December 31, 2004.

(b) On November 19, 2003, the Company completed a short-term unsecured debt financing in the aggregate amount of \$500,000. The notes bear interest of 8% and were due in full on November 19, 2004. The notes were convertible into common shares at a conversion rate equal to the lower of (i) 75% of the average market price for the 20 trading days ending on the 20th trading day subsequent to the effective date or (ii) \$0.75 per share. Pursuant to the note agreements, the Company also issued warrants to purchase up to 500,000 shares of the Company's common stock at an exercise price of \$1.00 per share. The warrants expire November 19, 2005.

The \$500,000 proceeds received was allocated between the debt and the warrants on a pro-rata basis. The value of the warrants was determined using a Black-Scholes option-pricing model. The allocated fair value of

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these warrants was \$241,655 and was recorded as a discount to the related debt. In addition, the conversion price was lower than the market value of the Company's common stock on the date of issue. As a result, an additional discount of \$258,345 was recorded for this beneficial conversion feature. The combined debt discount of \$500,000 was being amortized over the life of the debt using the effective interest method.

In conjunction with the debt financing, the Company issued warrants to purchase up to 100,000 shares of the Company's common stock at an exercise price of \$1.25 per share in satisfaction of a finder's fee. The value of these warrants was determined to be \$101,000 using a Black-Scholes option-pricing model. In addition, the Company incurred debt issuance costs of \$69,530 which were payable in cash. Total debt issuance costs of \$170,530 were recorded as an asset and amortized over the term of the debt.

In 2004, in conjunction with the June 25, 2004 transaction (Note 3(1)), the Company entered into a redemption agreement for its \$500,000 of short-term convertible debt. Payments on the convertible debt corresponded to payments received from the sale of common stock. As a result, the unamortized portion of the debt discount at the date of extinguishment of \$193,308 and the unamortized portion of the deferred loan costs of \$65,930 were recorded as a loss on extinguishment of debt. In addition to principal payments, the redemption payments included accrued interest and a premium payment of

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\$100,519. This premium payment has been recorded as a loss on extinguishment. As part of this redemption, the Company has repurchased the beneficial conversion feature amount of \$258,345 in 2004. Amortization of the debt discount up to the date of redemption was \$249,316 and \$57,377 for the years ended 2004 and 2003, respectively and amortization of deferred loans costs up to the date of redemption was \$85,031 and 19,569 for the years ended December 31, 2004 and 2003, respectively. These amounts were recorded as additional interest expense.

(c) On July 28, 2004, the Company entered into an agreement to issue 8% convertible debentures to Cornell in the amount of \$375,000 which is due together with interest on July 28, 2007. This debt has a subordinated security interest in the assets of the Company. The Company issued a second secured convertible debenture on October 7, 2004 which has the same conversion terms as the prior debenture and was issued on the date the Company filed a registration statement for the shares underlying both debentures. This is due together with interest on October 7, 2007 and has a subordinated security interest in the assets of the Company. The debentures are convertible into common stock at a price per share equal to the lesser of (a) an amount equal to 120% of the closing Volume Weighted Average Price (VWAP) of the common stock as of the Closing Date (\$1.88 on Closing Date) or (b) an amount equal to 80% of the lowest daily VWAP of the Company's common stock during the 5 trading days immediately preceding the conversion date. There was a floor conversion price of \$.75 until December 1, 2004.

Emerging Issues Task Force Issue 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios" ("EITF 98-5") requires the issuer to assume that the holder will not convert the instrument until the time of the most beneficial conversion. EITF 98-5 also requires that if the conversion terms are based on an unknown future amount, which is the case in item (b) above, the calculation should be performed using the commitment date which in this case is July 28, 2004 and October 7, 2004, respectively. As a result, the beneficial conversion amount was computed using 80% of the lowest fair market value for the stock for the five days preceding July 28, 2004 and October 7, 2004, respectively, which resulted in a beneficial conversion amount of \$254,006 and \$106,250, respectively. The beneficial conversion amount is being amortized over the term of the debt which is three years. At December 31, 2004, \$44,203 has been amortized.

In conjunction with the debt financing, the Company issued warrants to purchase up to 150,000 shares of the Company's common stock at an exercise price of \$1.00 per share in satisfaction of a finder's fee. The value of these warrants was determined to be \$144,000 using a Black-Scholes option-pricing model. In addition, the Company incurred debt issuance costs of \$162,500 which were payable in cash. Total debt issuance costs of \$306,500 were recorded as an asset and are being amortized over the term of the debt. Amortization of deferred loan costs of \$35,922 has been recognized as of December 31, 2004.

6. Loan From Shareholder

During 2002, a shareholder who is also an employee and member of the Company's board of directors, loaned the Company \$109,000. During 2003, the same shareholder loaned the Company an additional \$40,000. Interest on the loan is 5%, compounded monthly. Principal is due on December 31, 2009 and interest is payable quarterly in arrears beginning on June 30, 2003. Accrued interest was \$15,434 and \$7,431 at December 31, 2004 and 2003, respectively. Interest expense was \$8,003 and \$7,431 at December 31, 2004 and 2003, respectively.

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7. Subsequent Events

As of March 30, 2005, the Company held net proceeds of \$2.65 million in debt financing in escrow for the Company's benefit via a convertible debenture placed with an investor group led by DC Opportunity Fund Ltd. The Company anticipates that the proceeds will be released from escrow shortly. The new debenture instruments are convertible to common stock at a fixed price of \$0.75 per share. As an additional consideration, the new debenture holders will receive five-year warrants to purchase 4.5 million shares of Company common stock at an exercise price of \$1.06 per share and 175 day warrants, after an effective registration of the underlying shares, to purchase 3.2 million shares of Company common stock at an exercise price of \$1.01 per share.

On March 30, 2005, the Company authorized retirement of existing \$.65 million convertible debt instrument with Cornell Capital Partners. The debenture instrument had been reduced from the \$.75 million balance as of December 31, 2004.

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EXHIBIT INDEX

| Exhibit No. ----- | Description ----- |
|----------------------|--|
| 2.1* | Agreement and Plan of Reorganization dated April 23, 2002, among Provectus Pharmaceutical, Inc., a Nevada corporation ("Provectus"), Provectus Pharmaceuticals, Inc., a Tennessee corporation ("PPI"), and the stockholders of PPI identified therein, incorporated herein by reference to Exhibit 99 to the Company's Current Report on Form 8-K dated April 23, 2002, as filed with the SEC on April 24, 2002. |
| 2.2* | Agreement and Plan of Reorganization dated as of November 15, 2002 among the Company, PPI, Valley Pharmaceuticals, Inc., a Tennessee corporation formerly known as Photogen, Inc., H. Craig Dees, Ph.D., Dees Family Foundation, Walter Fisher, Ph.D., Fisher Family Investment Limited Partnership, Walt Fisher 1998 Charitable Remainder Unitrust, Timothy C. Scott, Ph.D., Scott Family Investment Limited Partnership, John T. Smolik, Smolik Family LLP, Eric A. Wachter, Ph.D., and Eric A. Wachter 1998 Charitable Remainder Unitrust, incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated November 19, 2002, as filed with the SEC on November 27, 2002. |
| 2.3* | Asset Purchase Agreement dated as of December 5, 2002 among Pure-ific Corporation, a Nevada corporation ("Pure-ific"), Pure-ific, L.L.C., a Utah limited liability company, and Avid Amiri and Daniel Urmann, incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated December 5, 2002, as filed with the SEC on December 20, 2002. |
| 2.4* | Stock Purchase Agreement dated as of December 5, 2002 among the Company, Pure-ific, and Avid Amiri and Daniel Urmann, incorporated herein by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K dated December 5, 2002, as filed with the SEC on December 20, 2002. |
| 3.1 | Restated Articles of Incorporation of Provectus, incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form |

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10-QSB for the fiscal quarter ended June 30, 2003, as filed with the SEC on August 14, 2003.

- 3.2 Bylaws of Provectus, incorporated herein by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-QSB for the fiscal quarter ended March 31, 2003, as filed with the SEC on May 9, 2003.
 - 4.1 Specimen certificate for the common shares, \$.001 par value per share, of Provectus Pharmaceuticals, Inc., incorporated herein by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, as filed with the SEC on April 15, 2003.
 - 4.2.1+ Convertible Secured Promissory Note and Warrant Purchase Agreement dated as of November 26, 2002 between the Company and Gryffindor Capital Partners I, L.L.C. ("Gryffindor"), incorporated herein by reference, incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed with the SEC on December 10, 2002.
 - 4.2.2 Letter Agreement dated January 31, 2003 between the Company and Gryffindor, incorporated by reference to Exhibit 4.2.2 to the Company's Quarterly Report on Form 10-QSB for the quarter ended March 31, 2003, as filed with the SEC on May 9, 2003.
 - 4.3 Amended and Restated Convertible Secured Promissory Note of the Company dated January 31, 2003, issued to Gryffindor, incorporated herein by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-QSB dated March 31, 2003, as filed with the SEC on May 9, 2003.
 - 4.4 Common Stock Purchase Warrant dated November 26, 2002, issued to Gryffindor, incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed with the SEC on December 10, 2002.
 - 4.5 Common Stock Purchase Warrant dated November 26, 2002, issued to Stuart Fuchs, incorporated herein by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed with the SEC on December 10, 2002.
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- 4.6 Stock Pledge Agreement dated as of November 26, 2002 between the Company and Gryffindor, incorporated herein by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed with the SEC on December 10, 2002.
 - 4.7 Guaranty dated November 26, 2002 from Xantech Pharmaceuticals, Inc., a Tennessee corporation and a wholly owned subsidiary of Provectus ("Xantech"), to Gryffindor, incorporated herein by reference to Exhibit 4.6 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed with the SEC on December 10, 2002.
 - 4.8 Form of Security Agreement between the Company and Gryffindor, incorporated herein by reference to Exhibit 4.7 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed with the SEC on December 10, 2002.
 - 4.9 Form of Patent and License Security Agreement between the Company and Gryffindor, incorporated herein by reference to Exhibit 4.8 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed

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with the SEC on December 10, 2002.

- 4.10 Form of Trademark Collateral Assignment and Security Agreement between the Company and Gryffindor, incorporated herein by reference to Exhibit 4.9 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed with the SEC on December 10, 2002.
- 4.11 Form of Copyright Security Agreement between the Company and Gryffindor, incorporated herein by reference to Exhibit 4.10 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed with the SEC on December 10, 2002.
- 4.12 Registration Rights Agreement dated as of November 26, 2002 between the Company and Gryffindor, incorporated herein by reference to Exhibit 4.11 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed with the SEC on December 10, 2002.
- 4.13 Shareholders' Agreement dated as of November 26, 2002 among Provectus, Gryffindor, H. Craig Dees, Ph.D., Dees Family Foundation, Walter Fisher, Ph.D., Fisher Family Investment Limited Partnership, Walt Fisher 1998 Charitable Remainder Unitrust, Timothy C. Scott, Ph.D., Scott Family Investment Limited Partnership, John T. Smolik, Smolik Family LLP, Eric A. Wachter, Ph.D., and Eric A. Wachter 1998 Charitable Remainder Unitrust, incorporated herein by reference to Exhibit 4.12 to the Company's Current Report on Form 8-K dated November 26, 2002, as filed with the SEC on December 10, 2002.
- 4.14 Warrant Agreement dated as of December 5, 2002 among Provectus, Avid Amiri and Daniel Urmann, incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K dated December 5, 2002, as filed with the SEC on December 20, 2002.
- 4.15 Form of Warrant issuable pursuant to the Warrant Agreement, incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K dated December 5, 2002, as filed with the SEC on December 20, 2002.
- 4.16 Promissory Note of the Company dated December 31, 2002, issued to Eric A. Wachter, incorporated herein by reference to Exhibit 4.16 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, as filed with the SEC on April 15, 2003.
- 4.17 Common Share Purchase Warrant dated January 29, 2003, issued to Investor-Gate.com, incorporated herein by reference to Exhibit 4.17 to the Company's Quarterly Report on Form 10-QSB for the fiscal quarter ended March 31, 2003, as filed with the SEC on May 9, 2003.
- 4.18 Form of 8% Convertible Debenture incorporated herein by reference to Annex I to Exhibit 10.16 to the Company's Registration Statement on Form S-2, as filed with the SEC on February 12, 2004.
- 4.19 Form of Warrant incorporated herein by reference to Annex IV to Exhibit 10.16 to the Company's Registration Statement on Form S-2, as filed with the SEC on February 12, 2004.
- 4.20 Registration Rights Agreement dated as of November 19, 2003 by and among the Company and the investors named therein incorporated by reference to Annex IV to Exhibit 10.16 to the Company's Registration Statement on Form S-2, as filed with the SEC on February 12, 2004.

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- 4.21 Registration Rights Agreement dated as of September 4, 2003 by and among the Company and Bruce A. Cosgrove and George F. Martin, incorporated herein by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-2, as filed with the SEC on February 12, 2004.
- 4.22 Form of Warrant issued to selling shareholders other than holders of 8% Convertible Debentures, incorporated herein by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-2, as filed with the SEC on February 12, 2004.
- 4.23 Registration Rights Agreement dated as of December 26, 2003 by and between the Company and The Research Foundation of State University of New York, incorporated herein by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-2, as filed with the SEC on February 12, 2004.
- 10.1 Consultant Compensation Agreement dated April 23, 2002 among Provectus and Russell Ratliff, Justeene Blankenship, Michael L. Labertew, and Phillip Baker, incorporated herein by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8 (Registration No. 333-86896), as filed with the SEC on April 24, 2002.
- 10.2** Provectus Pharmaceuticals, Inc. Amended and Restated 2002 Stock Plan, incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10QSB for the fiscal quarter ended June 30, 2003, as filed with the SEC on August 14, 2003.
- 10.3 Consulting Agreement dated August 15, 2002 between Provectus and Numark Capital Corporation ("Numark"), incorporated herein by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, as filed with the SEC on April 15, 2004.
- 10.4 Consulting Agreement dated August 28, 2002 between Provectus and Robert S. Arndt, incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 (Registration No. 333-99639), as filed with the SEC on September 17, 2002.
- 10.5 Consulting Agreement dated August 28, 2002 between Provectus and Nunzio Valerie, Jr., incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration No. 333-99639), as filed with the SEC on September 17, 2002.
- 10.6 Letter Agreement dated June 7, 2002 between Provectus and Nace Pharma, LLC, incorporated herein by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, as filed with the SEC on April 15, 2003..
- 10.7 Letter Agreement dated August 29, 2002 between Provectus and Nace Resources, Inc., incorporated herein by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, as filed with the SEC on April 15, 2004.
- 10.8 Confidentiality, Inventions and Non-competition Agreement between the Company and H. Craig Dees, incorporated herein by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, as filed with the SEC on April 15, 2004.
- 10.9 Confidentiality, Inventions and Non-competition Agreement between the Company and Timothy C. Scott, incorporated herein by reference to

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Exhibit 10.9 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, as filed with the SEC on April 15, 2004.

10.10 Confidentiality, Inventions and Non-competition Agreement between the Company and Eric A. Wachter, incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, as filed with the SEC on April 15, 2004.

10.11.1 Letter Agreement dated January 8, 2003 between the Company and Investor - Gate.com, incorporated herein by reference to Exhibit 10.11.1 to the Company's Quarterly Report on Form 10-QSB for the fiscal quarter ended March 31, 2003, as filed with the SEC on May 9, 2003.

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10.11.2 Termination Letter dated February 28, 2003 from the Company to Investor-Gate.com, incorporated herein by reference to Exhibit 10.11.2 to the Company's Quarterly Report on Form 10-QSB for the fiscal quarter ended March 31, 2003, as filed with the SEC on May 9, 2003.

10.12 Letter Agreement dated February 20, 2003 between the Company and SGI, incorporated herein by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-QSB for the fiscal quarter ended March 31, 2003, as filed with the SEC on May 9, 2003.

10.13 Letter Agreement dated March 27, 2003 between the Company and Josephberg Grosz & Co., Inc., incorporated herein by reference to Exhibit 10.13 to the Company's Quarterly Report on Form 10-QSB for the fiscal quarter ended March 31, 2003, as filed with the SEC on May 9, 2003.

10.14 Settlement Agreement dated as of June 16, 2003 among Kelly Adams, Justeene Blankenship, Nicholas Julian, and Pacific Management Services, Inc.; and Provectus and Xantech, incorporated herein by reference to Exhibit 10.14 to the Company's Current Report on Form 8-K dated June 16, 2003, as filed with the SEC on June 26, 2003.

10.15 Material Transfer Agreement dated as of July 31, 2003 between Schering-Plough Animal Health Corporation and Provectus, incorporated herein by reference to Exhibit 10.15 to the Company's Quarterly Report on Form 10-QSB for the fiscal quarter ended June 30, 2003, as filed with the SEC on August 14, 2003.

10.16 Securities Purchase Agreement dated as of November 19, 2003 by and among the Company and the lenders named therein, incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-2, as filed with the SEC on February 12, 2004

10.17 Securities Purchase Agreement dated June 25, 2004 by and among the Company and A.I. International Corporate Holdings, Ltd. and Castlerigg Master Investments, Ltd., incorporated herein by reference to the Company's Registration Statement on Form S-2, as filed with the SEC on October 7, 2004

10.18 Standby Equity Distribution dated July 28, 2004 by and among the Company and Cornell Capital Partners, LP, incorporated herein by reference to the Company's Registration Statement on Form S-2, as filed with the SEC on October 7, 2004

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- 10.19 Securities Purchase Agreement dated July 28, 2004 by and among the Company and Cornell Capital Partners, LP, incorporated herein by reference to the Company's Registration Statement on Form S-2, as filed with the SEC on October 7, 2004
- 10.20+ Second Amended and Restated Senior Secured Convertible Note by and between the Company and Gryffindor Capital Partners I, L.L.C.
- 21.1+ List of Subsidiaries.
- 23.1+ Consent of BDO Seidman, LLP.
- 31.1+ Certification of CEO pursuant to Rules 13a - 14(a) of the Securities Exchange Act of 1934.
- 31.2+ Certification of CFO pursuant to Rules 13a-14(a) of the Securities Exchange Act of 1934.
- 32+ Certification Pursuant to 18 U.S.C. ss. 1350.
-

* The Company agrees by this filing to supplementally furnish to the SEC, upon request, a copy of the exhibits and/or schedules to this agreement.

** Management compensation contract or plan.

+ Filed herewith.

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