PROVECTUS PHARMACEUTICALS INC
Form 10KSB
March 30, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-KSB

(Mark One)

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

For the fiscal year ended December 31, 2005; OR

o 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 is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. o
Note - Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d)

of the Exchange Act from their obligations under those Sections.

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 xNo o
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. x

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

The issuer’s revenues for the most recent fiscal year were $6,536.

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of February 13, 2006, was $31,212,267 (computed on the basis of $0.88 per share).

The number of shares outstanding of the issuer's stock, $0.001 par value per share, as of February 13, 2006 was 35,468,485.

Documents incorporated by reference in Part III hereof: Proxy Statement for 2006 Annual Meeting of Stockholders.

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

Table of Contents **Page**

PART I

Item 1. Description of Business.

History

Provectus Pharmaceuticals, Inc., formerly known as "Provectus 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:

- prescription drugs, medical and other devices (including laser devices) and over-the-counter pharmaceutical products in the fields of dermatology and oncology; and

- 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.

(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;"
- 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 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;

3

- 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. We now intend to license this product to a third party with experience in the institutional sales market.

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 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 online sales of the antibacterial hand spray. During 2005, most of our sales were generated from customers accessing our website for Pure-ific and making purchases online. We now intend to license the Pure-ific product and sell the underlying assets.

Acne

A number of dermatological conditions, including acne and other blemishes 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 acne and other blemishes. 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 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 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 the use of Xantryl with 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 have decided to prioritize further clinical development of Xantryl

for treatment of psoriasis and eczema rather than AK at this time since the market is much larger for psoriasis and eczema.

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 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 worked 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 FDA in 2004 setting the stage for two Phase 1 clinical trials; namely, treating metastatic melanoma and recurrent breast carcinoma. We started both of these Phase 1 clinical trials in 2005.

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 expanding clinical studies of direct injection of Provecta into breast tumors while conducting Phase 1 clinical studies of our indication for Provecta in recurrent breast carcinoma.

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 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.

Metastatic Melanoma. Melanoma is expected to strike 62,000 people in the U.S. this year, leading to 7,600 deaths. The incidence of melanoma in Australia, where our Phase 1 clinical study is currently underway, is 4X that of the U.S. There have been no significant advances in the treatment of melanoma for approximately 30 years. We are evaluating options for expanding clinical studies of direct injection of Provecta into melanoma lesions while conducting Phase 1 clinical studies of our indication for Provecta in Stage 3 metastatic melanoma.

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 dermatological 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 have conducted 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 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 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 maximizing shareholder value and advancing our corporate objectives in conjunction with our OTC product licensure, our current product development and maintaining our intellectual property portfolio.

Production

We have determined that the most efficient use of our capital in further developing our OTC products is to license the products and sell the underlying assets for upfront consideration.

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 have commenced limited sales of Pure-ific, our antibacterial hand spray. We sold small amounts of this product during 2004 and 2005. 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 through licensure and partnership arrangements, and through potential merger and acquisition candidates.

In addition to developing and selling products ourselves on a limited basis, 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:

U.S. Patent No.	Title	Issue Date	Expiration Date
5,829,448	Method for improved selectivity in photo-activation of molecular agents	November 3, 1998	October 30, 2016
5,832,931	Method for improved selectivity in photo-activation and detection of molecular diagnostic agents	November 10, 1998	October 30, 2016

5,998,597	Method for improved selectivity in photo-activation of molecular agents	December 7, 1999	October 30, 2016
6,042,603	Method for improved selectivity in photo-activation of molecular agents	March 28, 2000	October 30, 2016
6,331,286	Methods for high energy phototherapeutics	December 18, 2001	December 21, 2018
6,451,597	Method for enhanced protein stabilization and for production of cell lines useful for production of such stabilized proteins	September 17, 2002	April 6, 2020
6,468,777	Method for enhanced protein stabilization and for production of cell lines useful for production of such stabilized proteins	October 22, 2002	April 6, 2020
6,493,570	Method for improved imaging and photodynamic therapy	December 10, 2002	December 10, 2019
6,495,360	Method for enhanced protein stabilization and for production of cell lines useful for production of such stabilized proteins	December 17, 2002	April 6, 2020
6,519,076	Methods and apparatus for optical imaging	February 11, 2003	October 30, 2016
6,525,862	Methods and apparatus for optical imaging	February 25, 2003	October 30, 2016
6,541,223	Method for enhanced protein stabilization and for production of cell lines useful for production of such stabilized proteins	April 1, 2003	April 6, 2020
6,986,740	Ultrasound contrast using halogenated xanthenes	January 17, 2006	TBD
6,991,771	Improved intracorporeal medicaments for High energy phototherapeutic treatment of disease	January 31, 2006	TBD

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 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 "SPAH", the animal-health subsidiary of Schering-Plough Corporation, a major international pharmaceutical company. This Material Transfer Agreement is still in effect through 2005. We refer to this agreement in this report as the "Material Transfer Agreement." Under the Material Transfer Agreement, we will provide SPAH with access to some of our patented technologies to permit SPAH to evaluate those technologies for use in animal-health applications. If SPAH determines that it can commercialize our technologies, then the Material Transfer Agreement obligates us and SPAH to enter into a license agreement providing for us to license those technologies to SPAH 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 SPAH 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 SPAH will determine that it can commercialize our technologies or that the goals required for us to obtain progress payments from SPAH will be achieved.

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.

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 our 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

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 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 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.

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

Personnel

Executive Officers

As of March 29, 2006, our executive officers are:

H. Craig Dees, Ph.D., 54, 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., 48, 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., 43, 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.

Peter R. Culpepper, CPA, MBA, 46, 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 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.

Employees

We currently employ five 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 1A. Risk Factors.

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:

Our technologies are in early stages of development. We have generated minimal initial revenues from sales and operations in 2005 and 2004, but we do not expect to generate sufficient revenues to enable us to be profitable for several calendar quarters unless we sell and/or license our technologies. We must raise substantial additional funds beyond 2006 in order to fully implement our integrated business plan, including execution of the next phases in clinical development of our pharmaceutical products. 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 unless we are acquired by another Company. We intend to proceed as rapidly as possible with the asset sale and licensure 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 beyond 2006 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 in 2007.

As of December 31, 2005, we had $878,941 in convertible debt, net of a debt discount of $1,064,895 and $65,055 of accrued interest on our balance sheet, consisting of $1,475,000 in principal and $61,408 in accrued but unpaid interest owed to holders of our convertible debentures due on March 30, 2007 and $468,836 in principal and $3,647 in accrued interest owed to holders of our convertible debentures due on November 26, 2006. Because of the convertible nature of the debt owed 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 beyond 2006, 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 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.

We must raise additional capital from external sources to execute our business plan beyond 2006. We plan to issue debt securities, capital stock, or a combination of these securities, if necessary depending on licensure and asset sale discussions. 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 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 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 sold through a combination of asset sale and licensure in the marketplace or that we will have adequate capital to further develop these products, if necessary, which are an important factor in the future success of our business.

We recently have focused on marketing Pure-ific, one of our OTC products, on a limited basis to establish proof of concept. We have recognized minimal revenue from this product, as the sales of this product has not been material. In order for this product, and our other OTC products, to become commercially successful, unless we license and/or sell the underlying assets, we must increase significantly our distribution of them. Increasing distribution of our 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 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 plan to allocate 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 would likely require additional capital beyond 2006 to continue as a going concern.

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, 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.

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 (owned by Pfizer),
- 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. 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

are current technology is adequate for our 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, medical device and OTC products. Also, as of December 31, 2005, we owe $179,170 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 five employees in total, 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 five 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 in addition to the full-time lab technician that we have recently employed, 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 which has increased significantly from 2004 to 2005.

17

During the twelve-month period ended December 31, 2005, the sale price of our common stock fluctuated from $1.25 to $0.52 per share. We believe that our common stock is subject to wide price fluctuations because of several factors, including:

o absence of meaningful earnings and ongoing need for 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 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 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.

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 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 we 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 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 pennies 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 1B. Unresolved Staff Comments.

None.

Item 2. Description of Property.

We currently lease approximately 6,000 square feet of space outside of Knoxville, Tennessee for our corporate office and operations. Our monthly rental charge for these offices is approximately $4,000 per month, and the lease is renewed on an annual basis. We believe that these offices generally are adequate for our needs currently and in the immediate future.

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, 2005, we did not submit any matters to a vote of our stockholders.

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, 2004:

	High	Low
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
2005		
First Quarter (January 1 to March 31)	$ 1.25	$ 0.64
Second Quarter (April 1 to June 30)	$ 0.85	$ 0.52
Third Quarter (July 1 to September 30)	$ 0.99	$ 0.60
Fourth Quarter (October 1 to December 31)	$ 1.14	$ 0.77

The closing price for our common stock on February 13, 2006 was $0.88. 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 February 13, 2006, we had 1,888 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 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 quarter ended December 31, 2005, 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 as follows:

During the three months ended December 31, 2005, the Company completed a private placement transaction with 62 accredited investors pursuant to which the Company sold 10,065,605 shares of common stock at a purchase price of $0.75 per share of which 5,126,019 are committed to be issued at December 31, 2005, for an aggregate purchase price of $7,549,202. In connection with the sale of common stock, the Company also issued warrants to the investors to

purchase up to 12,582,009 shares of common stock at an exercise price of $0.935 per share. The Company paid $959,540, issued 46,667 shares of common stock at a fair market value of $46,467, issued 30,550 warrants, and committed to issue 950,461 shares of common stock at a fair market value of $894,593 to a syndicate led by Network 1 Financial Securities, Inc. as placement agent for this transaction which is accrued at December 31, 2005. The cash and common stock costs have been off-set against the proceeds received. 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 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.

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

Our ability to continue as a going concern is assured due to our financing completed in December, 2005. At the current rate of expenditures, we will not need to raise additional capital until late 2007.

We have implemented our integrated business plan, including execution of the current and next phases in clinical development of our pharmaceutical products and continued execution of research programs for new research initiatives.

We intend to proceed as rapidly as possible with the asset sale and licensure of our 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 medical device and biotech intellectual property portfolio. Although we believe that there is a reasonable basis for our expectation that we will become profitable due to the asset sale and licensure of our OTC products, 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 five employees during the immediate future, but we have added additional consultants and anticipate adding employees in the next 12 months. Our current plans also include minimal purchases of new property, plant and equipment, and increased research and development for additional clinical trials.

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 2006 we plan to build on that foundation to increase shareholder value through careful control of expenditures, preparation for the asset sale and licensure of our OTC products, medical device and biotech technologies, and issuance of equity only when it makes sense to the Company and primarily for purposes of attracting strategic investors.

In the short term, we intend to develop our business by selling the OTC assets and licensing our existing OTC products, principally Pure-Stick, GloveAid and Pure-ific. We will also sell and/or license our medical device and biotech technologies. In the longer term, we expect to continue the process of developing, testing, and obtaining the clearance and ultimately approval of the U. S. Food and Drug Administration for prescription drugs in particular. Additionally, we have restarted 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.

Comparison of the Years Ended December 31, 2005 and 2004.

Revenues. OTC Product Revenue decreased by $13,176 in 2005 to $5,552 from $18,728 in 2004. The decrease in OTC Product Revenue resulted primarily from lower sales of Pure-ific in retail stores because we discontinued our proof of concept program with major distributors and retailers. OTC Product Revenue continues due to online sales. Medical Device Revenue decreased by $12,141 in 2005 to $984 from $13,125 in 2004. The decrease in Medical Device Revenue resulted primarily due to a large beta unit sale in the 2004 that was not repeated in 2005, partially offset by sales of three smaller devices in 2005.

Research and development. The Company has completed the planning phase for the major research and development projects anticipated in the next 12 months. The Company’s Phase 1 metastatic melanoma and breast carcinoma clinical trials are expected to be completed in early to mid 2006 for less than $1,000,000 in the aggregate. At that time the planning phase for the expected Phase 2 trials will be completed, which cost approximately $1,000,000 in the aggregate. The Company’s Phase 2 psoriasis trial is expected to commence in mid to late 2006 and will cost approximately $1,500,000 over 12 to 24 months. The Company’s Phase 1 liver cancer trial is expected to cost less than $500,000 in total, and is expected to commence in mid 2006. Research and development costs comprising the total of $2,044,391 for 2005 included depreciation expense of $1,708, consulting of $805,915, lab supplies of $111,504, insurance of $120,493, legal of $208,368, payroll of $747,197, and rent and utilities of $49,206. The research and development costs are higher for 2005 because the Company has initiated two Phase 1 clinical trials under the aegis of the Food & Drug Administration (FDA). 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.

General and administrative. General and administrative expenses increased by $1,308,493 in 2005 to $2,999,334 from $1,690,841 in 2004. The increase resulted primarily from higher consulting and payroll expenses for general corporate purposes. $733,269 of this increase was from consulting and $390,571 was from payroll expenses.

CASH FLOW

As of February 13, 2006, we held approximately $6,600,000 in cash. At our current cash expenditure rate, this amount will be sufficient to meet our needs. We have been increasing our expenditure rate by accelerating some of our

research programs for new research initiatives; in addition, we are seeking to improve our cash flow through the asset sale and licensure of our OTC products. However, we cannot assure you that we will be successful in selling the OTC assets and licensing our existing OTC products. Moreover, even if we are successful in improving our current cash flow position, we nonetheless plan to require additional funds to meet our long-term needs in 2007 and beyond. We anticipate these funds will come from the proceeds of private placements, the exercise of existing warrants outstanding, 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. Excess cash will be used to finance the current and next phases in clinical development of our pharmaceutical products. We anticipate that any required funds for our operating and development needs beyond 2006 will come from the proceeds of private placements, the exercise of existing warrants outstanding, 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

In November 2004, the FASB issued Statement of Financial Accounting Standards No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4.* The purpose of this statement is to clarify the accounting of abnormal amounts of idle facility expense, freight, handling costs and waste material. ARB No. 43 stated that under some circumstances these costs may be so abnormal that they are required to be treated as current period costs. SFAS 151 requires that these costs be treated, as current period costs regardless if they meet the criteria of "so abnormal." In addition, the statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provision of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS 151 is not expected to have a material impact on the Company's results of operations or financial position.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29.* SFAS 153 is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005, with earlier application permitted. The adoption of SFAS 153 is not expected to have a material impact on the Company's results of operations or financial position.

In December 2004, the FASB issued SFAS No. 123(R), *Share-Based Payments (revised 2004)*. This statement eliminates the option to apply the intrinsic value measurement provisions of APB Board Opinion No. 25, *Accounting for Stock Issued to Employees*, to stock compensation awards issued to employees. Rather, the Statement requires companies to measure the cost of employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. That cost will be recognized over the period during which an employee is required to provide services in exchange for the award — the requisite service period (usually the vesting period). In March 2005, the SEC staff expressed their views with respect to SFAS No. 123(R) in Staff Accounting Bulletin No. 107, *Share-Based Payment*, (SAB 107). SAB 107 provides guidance on valuing options. SFAS 123(R) will be effective for the Company's fiscal year beginning January 1, 2006. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

In March 2005, the FASB issued FASB Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations*, (FIN 47). FIN 47 is an interpretation of SFAS No. 143, *Asset Retirement Obligations*, which was issued in June 2001. FIN 47 was issued to address diverse accounting practices that have developed with regard to the timing of liability recognition for legal obligations associated with the retirement of a tangible long-lived asset in which the timing and/or method of settlement are conditional on a future event that may or may not be within the control of the entity. According to FIN 47, uncertainty about the timing and/or method of settlement of a conditional asset retirement obligation should be factored into the measurement of the liability when sufficient information exists. FIN 47 also clarifies when an entity would have sufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN 47 is effective no later than December 31, 2005 for the Company. The adoption of FIN 47 is not expected to have a material impact on the Company's results of operations or financial position.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections,* a replacement of APB Opinion No. 20 and Statement No. 3. SFAS 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS 154 applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement that does not include specific transition provisions. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS 154 is not expected to have a material impact on the Company's results of operations or financial position.

In September 2005, the Emerging Issues Task Force (EITF) ratified Issue No. 05-8, "Income Tax Consequences of Issuing Convertible Debt with a Beneficial Conversion Feature." When a company issues convertible debt with a beneficial conversion feature, the debt is bifurcated into a liability component and an equity component in accordance with EITF Issues No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios" and No. 00-27, "Application of Issue No. 98-5 to Certain Convertible Instruments." The equity component is measured at the intrinsic value of the beneficial conversion feature on the commitment date. For income tax purposes, all of the proceeds are recorded as a liability and nothing is recorded in shareholders' equity. The issues are whether the issuance of convertible debt with a beneficial conversion feature results in a basis difference and, if so, whether that basis difference is a temporary difference under FASB Statement No. 109, *Accounting for Income Taxes.* The adoption of EITF 05-8 is not expected to have a material impact on the Company's results of operations or financial position. However, we do expect the adoption of EITF 05-8 to result in a material change to our income tax disclosures.

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.

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.

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 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 December 31, 2005. 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.

Item 8B. Other Information.

None.

Part III

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

Except as set forth below, the information called for by this item with respect to our executive officers as of March 29, 2006 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 June 22, 2006, 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 five 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 June 22, 2006, 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 June 22, 2006, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

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 June 22, 2006, 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.

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 June 22, 2006, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

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, 2005 to be signed on its behalf by the undersigned, thereunto duly authorized.

PROVECTUS PHARMACEUTICALS, INC.

Date: March 29, 2006

By: /s/ H. Craig Dees

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

/s/ H. Craig Dees

Name: H. Craig Dees, Ph.D.
Title: Chief Executive Officer (principal executive officer) and Chairmain of the Board
Date: March 29, 2006

/s/ Peter R. Culpepper

Name: Peter R. Culpepper
Title: Chief Financial Officer (principal financial officer and principal accounting officer)
Date: March 29, 2006

/s/ Timothy C. Scott

Name: Timothy C. Scott, Ph.D.
Title: President and Director
Date: March 29, 2006

/s/ Eric A. Wachter

Name: Eric A. Wachter
Title: Vice President - Pharmaceuticals and Director
Date: March 29, 2006

/s/ Stuart Fuchs

Name: Stuart Fuchs
Title: Director
Date: March 29, 2006

28

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, 2005 and 2004 and the related consolidated statements of operations, stockholders' equity, and cash flows for the period from January 17, 2002 (inception) to December 31, 2005 and for each of the two years in the period ended December 31, 2005. 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, 2005 and 2004, and the results of its operations and its cash flows for the period from January 17, 2002 (inception) to December 31, 2005 and for each of the two years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

/s/BDO Seidman, LLP

Chicago, Illinois
March 10, 2006

PROVECTUS PHARMACEUTICALS, INC.
(A Development-Stage Company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2005	December 31, 2004
Assets		
Current Assets		
Cash and cash equivalents	$ 6,878,990	$ 10,774
Prepaid expenses and other current assets	67,962	114,724
Prepaid consulting expense	-	205,427
Prepaid commitment fee, net of amortization of $38,326 in 2004	-	272,540
Total Current Assets	6,946,952	603,465
Equipment and Furnishings, less accumulated depreciation of $368,279 and $366,571	12,287	-
Patents, net of amortization of $2,091,657 and $1,420,537	9,623,788	10,294,908
Deferred loan costs, net of amortization of $247,802 and $35,922	709,092	270,578
Other assets	27,000	27,000
	$ 17,319,119	$ 11,195,951
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable - trade	$ 90,124	$ 154,214
Accrued compensation	179,170	156,377
Accrued common stock costs	964,676	-
Accrued consulting expense	692,512	-
Other accrued expenses	61,500	6,240
Accrued interest	65,055	43,670
March 2005 convertible debt, net of debt discount of $884,848 in 2005	221,401	-
November 2005 convertible debt, net of debt discount of $134,008 in 2005	334,828	-
Gryffindor convertible debt, net of debt discount of $95,157 in 2004	-	1,090,802
Total Current Liabilities	2,609,266	1,451,303
Loan From Stockholder	-	149,000
Cornell convertible debt, net of debt discount of $316,053 in 2004	-	433,947

March 2005 convertible debt, net of debt discount of $46,039 in 2005		322,712		-
Stockholders' Equity				
Common stock; par value $.001 per share; 100,000,000 shares authorized; 27,822,977 and 16,133,876 shares issued and outstanding, respectively		27,823		16,134
Paid-in capital		40,689,144		23,711,540
Deficit accumulated during the development stage		(26,329,826)		(14,565,973)
Total Stockholders' Equity		14,387,141		9,161,701
	$	17,319,119	$	11,195,951

See accompanying notes to financial statements.

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

	Year Ended December 31, 2005	Year Ended December 31, 2004	Cumulative Amounts from January 17, 2002 (Inception) Through December 31, 2005
Revenues			
OTC Product Revenue	$ 5,552	$ 18,728	$ 24,280
Medical Device Revenue	984	13,125	14,109
Total revenues	6,536	31,853	38,389
Cost of Sales	3,560	10,781	14,341
Gross Profit	2,976	21,072	24,048
Operating Expenses			
Research and development	$ 2,044,391	$ 1,291,817	$ 4,111,846
General and administrative	2,999,334	1,690,841	13,195,371
Amortization	671,120	671,120	2,091,657
Total operating loss	(5,711,869)	(3,632,706)	(19,374,826)
Gain on sale of fixed assets	-	-	55,000
Loss on extinguishment of debt	(724,455)	(101,412)	(825,867)
Net interest expense	(5,327,529)	(610,407)	(6,184,133)
Net Loss	$ (11,763,853)	$ (4,344,525)	$ (26,329,826)
Basic and Diluted Loss Per Common Share	$ (0.62)	$ (0.31)	
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	18,825,670	14,122,559	

See accompanying notes to financial statements.

F-3

PROVECTUS PHARMACEUTICALS, INC.
(A Development-Stage Company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock				
	Number of Shares	Par Value	Paid-in Capital	Accumulated Deficit	Total
Balance, at January 17, 2002	$ -	$ -	$ -	$ -	$ -
Issuance to founding shareholders	6,000,000	6,000	(6,000)	-	-
Sale of stock	50,000	50	24,950	-	25,000
Issuance of stock to employees	510,000	510	931,490	-	932,000
Issuance of stock for services	120,000	120	359,880	-	360,000
Net loss for the period from January 17, 2002 (inception) to April 23, 2002 (date of reverse merger)	-	-	-	(1,316,198)	(1,316,198)
Balance, at April 23, 2002	$ 6,680,000	$ 6,680	$ 1,310,320	$ (1,316,198)	$ 802
Shares issued in reverse merger	265,763	266	(3,911)	-	(3,645)
Issuance of stock for services	1,900,000	1,900	5,142,100	-	5,144,000
Purchase and retirement of stock	(400,000)	(400)	(47,600)	-	(48,000)
Stock issued for acquisition of Valley Pharmaceuticals	500,007	500	12,225,820	-	12,226,320
Exercise of warrants	452,919	453	-	-	453
Warrants issued in connection with convertible debt	-	-	126,587	-	126,587
Stock and warrants issued for acquisition of Pure-ific	25,000	25	26,975	-	27,000
Net loss for the period from April 23, 2002 (date of reverse merger) to December 31, 2002	-	-	-	(5,749,937)	(5,749,937)
Balance, at December 31, 2002	$ 9,423,689	$ 9,424	$ 18,780,291	$ (7,066,135)	$ 11,723,580
Issuance of stock for services	764,000	764	239,036	-	239,800
Issuance of warrants for services	-	-	145,479	-	145,479
Stock to be issued for services	-	-	281,500	-	281,500
Employee compensation from stock options	-	-	34,659	-	34,659
Issuance of stock pursuant to Regulation S	679,820	680	379,667	-	380,347
Beneficial conversion related to convertible debt	-	-	601,000	-	601,000
Net loss for the year ended December 31, 2003	-	-	-	(3,155,313)	(3,155,313)
Balance, at December 31, 2003	$ 10,867,509	$ 10,868	$ 20,461,632	$ (10,221,448)	$ 10,251,052
Issuance of stock for services	733,872	734	449,190	-	449,923
Issuance of warrants for services	-	-	495,480	-	495,480
Exercise of warrants	132,608	133	4,867	-	5,000
	-	-	15,612	-	15,612

Employee compensation from stock options					
Issuance of stock pursuant to Regulation	2,469,723	2,469	790,668	-	793,137
Issuance of stock pursuant to Regulation D	1,930,164	1,930	1,286,930	-	1,288,861
Beneficial conversion related to convertible debt	-	-	360,256	-	360,256
Issuance of convertible debt with warrants	-	-	105,250	-	105,250
Repurchase of beneficial conversion feature	-	-	(258,345)	-	(258,345)
Net loss for the year ended December 31, 2004	-	-	-	(4,344,525)	(4,344,525)
Balance, at December 31, 2004	$ 16,133,876	$ 16,134	$ 23,711,540	$ (14,565,973)	$ 9,161,701
Issuance of stock for services	226,733	227	152,058	-	152,285
Issuance of stock for interest payable	263,721	264	195,767	-	196,031
Issuance of warrants for services	-	-	1,534,405	-	1,534,405
Issuance of warrants for contractual obligations	-	-	985,010	-	985,010
Exercise of warrants and stock options	1,571,849	1,572	1,438,223	-	1,439,795
Employee compensation from stock options	-	-	15,752	-	15,752
Issuance of stock pursuant to Regulation D	6,221,257	6,221	6,506,955	-	6,513,176
Debt conversion to common stock	3,405,541	3,405	3,045,957	-	3,049,362
Issuance of warrants with convertible debt	-	-	1,574,900	-	1,574,900
Beneficial conversion related to convertible debt	-	-	1,633,176	-	1,633,176
Beneficial conversion related to interest expense	-	-	39,529	-	39,529
Repurchase of beneficial conversion feature	-	-	(144,128)	-	(144,128)
Net loss for the year ended 2005	-	-	-	(11,763,853)	(11,763,853)
Balance, at December 31, 2005	27,822,977	$ 27,823	$ 40,689,144	$ (26,329,826)	$ 14,387,141

See accompanying notes to financial statements.

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

	Year Ended December 31, 2005	Year Ended December 31, 2004	Cumulative Amounts from January 17, 2002 (Inception) through December 31, 2005
Cash Flows From Operating Activities			
Net loss	$ (11,763,853)	$ (4,344,525)	$ (26,329,826)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	1,708	121,811	391,280
Amortization of patents	671,120	671,120	2,091,657
Amortization of original issue discount	2,293,251	360,663	2,780,826
Amortization of commitment fee	272,540	38,326	310,866
Amortization of prepaid consultant expense	274,337	606,888	1,127,187
Amortization of deferred loan costs	1,411,970	120,953	1,552,492
Loss on extinguishment of debt	724,455	101,412	825,867
Loss on exercise of warrants	236,146	-	236,146
Beneficial conversion of convertible interest	39,529	-	39,529
Convertible interest	266,504	-	266,504
Compensation through issuance of stock options			