PROVECTUS PHARMACEUTICALS INC
Form 10-K/A
July 25, 2011

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

FORM 10-K/A
Amendment No. 1

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

For the fiscal year ended December 31, 2010

¨ 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 000-09410

PROVECTUS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada	90-0031917
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

7327 Oak Ridge Highway, Suite A, Knoxville, Tennessee 37931
(Address of principal executive offices) (Zip Code)

866-594-5999
(Registrant's telephone number, including area code)

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

None

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

Common Stock, par value $.001 per share
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ¨ Yes x No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ¨ Yes x No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ¨ Yes ¨ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 30, 2010, was $79,391,581.80 (computed on the basis of $1.10 per share).

The number of shares outstanding of the registrant's common stock, par value $.001 per share, as of March 7, 2011 was 99,800,071.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III is incorporated by reference to portions of the definitive proxy statement to be filed within 120 days after December 31, 2010, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on June 23, 2011.

EXPLANATORY NOTE

Provectus Pharmaceuticals, Inc. (the "Company," "we," "us" and "our") is filing this Amendment No. 1 to its Annual Report on Form 10-K/A (the "Amended 10-K") to amend its Annual Report on Form 10-K for the year ended December 31, 2010, filed with the Securities and Exchange Commission (the "SEC") on March 16, 2011 (the "Original 10-K"). This Amended 10-K is being filed to amend and restate our consolidated financial statements and related disclosures for the year ended December 31, 2010 as discussed in Note 13 to the accompanying restated financial statements.

Background of the Restatement

On July 19, 2011, the Board of Directors of the Company, serving in its role as the audit committee, after consultation with and upon recommendation from management of the Company, concluded that its audited financial statements included in the Company's Original 10-K for the year ended December 31, 2010 and its unaudited financial statements included in the Company's quarterly report on Form 10-Q for the quarterly period ended March 31, 2011 cannot be relied upon due to an error relating to the classification of the Company's outstanding 8% convertible preferred stock (the "Preferred Stock") as temporary stockholders' equity rather than permanent stockholders' equity. The Certificate of Designation for the Preferred Stock provides the holders of Preferred Stock a non-participating liquidation preference upon the liquidation, winding-up or dissolution of the Company or upon the occurrence of a deemed liquidation event. A deemed liquidation event includes a merger or other corporate reorganization that results in a change in control of the Company or any transaction in which all or substantially all of the Company's assets are sold. In the Original 10-K, the Company believed that redemption of the Preferred Stock could result from a deemed liquidation event that was not under the control of the Company. As a result, the Preferred Stock was classified as redeemable preferred stock outside of stockholders' equity on the consolidated balance sheets. The Company has since determined that the events that would result in a deemed liquidation event are under the control of the Board of Directors. As a result, at December 31, 2010, the Preferred Stock has been reclassified from temporary stockholders' equity into permanent stockholders' equity. An explanation of the error and its impact on the Company's financial statements is contained in Note 13 to the financial statements contained in Part II of this report.

Restatement of Other Financial Statements

Along with the filing of this Amended 10-K, we are concurrently filing an amendment to our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2011. The amendment to our Quarterly Report on Form 10-Q is being filed to restate our unaudited financial statements and related financial information for the period contained in the report to reflect the reclassification of the Preferred Stock from temporary stockholders' equity to permanent stockholders' equity.

Amendments to the Original 10-K

For the convenience of the reader, this Amended 10-K sets forth the Original 10-K, as modified and superseded where necessary to reflect the restatement. The following items have been amended principally as a result of, and to reflect, the restatement:

- Part II — Item 8. Financial Statements and Supplementary Data;
- Part II — Item 9A. Controls and Procedures; and
- Part IV — Item 15. Exhibits and Financial Statement Schedules.

In accordance with applicable SEC rules, this Amended 10-K includes certifications from our Chief Executive Officer and Chief Financial Officer dated as of the date of this filing. Except for the items noted above, no other information included in the Original 10-K is being amended by this Amended 10-K. The Amended 10-K continues to speak as of the date of the Original 10-K, and we have not updated the filing to reflect events occurring subsequently to the Original 10-K date, other than those associated with the restatement of the Company's financial statements. Accordingly, this Amended 10-K should be read in conjunction with our filings made with the SEC subsequent to the filing of the Original 10-K.

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Amendment No. 1 to our Annual Report on Form 10-K/A 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 Amendment No. 1 to our Annual Report on Form 10-K/A. 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 Amendment No. 1 to our Annual Report on Form 10-K/A 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.

PART I

ITEM 1. BUSINESS.

General

Provectus Pharmaceuticals, Inc., a Nevada corporation, together with its seven wholly owned subsidiaries managed on a consolidated basis, referred to herein as "we," "us," and "our," is a development-stage pharmaceutical company that is primarily engaged in developing ethical pharmaceuticals for oncology and dermatology indications. Our goal is to develop alternative treatments that are safer, more effective, less invasive and more economical than conventional therapies. We develop and intend to license or market and sell our two prescription drug candidates, PV-10 and PH-10. We also hold patents and other intellectual property which we believe may be used in over-the-counter products, which we refer to as OTC products, and medical device technologies. We have transferred all our intellectual property related to OTC products and medical device technologies to our subsidiaries and have designated such subsidiaries as non-core to our primary business of developing our oncology and dermatology prescription drug candidates.

Prescription Drugs

We focus on developing our prescription drug candidates PV-10 and PH-10. We are developing PV-10 for treatment of several life threatening cancers including metastatic melanoma, liver cancer, and breast cancer. We are developing PH-10 to provide minimally invasive treatment of chronic severe skin afflictions such as psoriasis and atopic dermatitis, a type of eczema. We believe that our prescription drug candidates will be safer and more specific than currently existing products. All of our prescription drug candidates are in either the pre-clinical or clinical trial stage.

The table below sets forth our two prescription drug candidates and our progress in developing those candidates for the indications shown:

PV-10 Melanoma	· Phase 2 study completed May 2010 · End-of-Phase 2 FDA meeting April 2010 · Phase 2 treatments completed September 2009 · Phase 2 recruitment completed May 2009 · Phase 2 study initiated Sep 2007 · Orphan drug status Jan 2007
PH-10 Psoriasis	· Phase 2c randomized study initiated Dec 2010 · Phase 2 study completed Apr 2010 · Phase 2 recruitment completed Oct 2009 · Replacement Phase 2 initiated Jul 2009 due to dose regimen change · Phase 2 study initiated Nov 2007
PH-10 Atopic Dermatitis	· Phase 2 study completed Sep 2009 · Phase 2 recruitment completed Jun 2009 · Phase 2 study initiated Jun 2008
PV-10 Breast Cancer	· Phase 1 study completed Jul 2008 · Phase 1 initial cohort treatment completed April 2006 · Phase 1 study initiated October 2005

PV-10 Liver Metastasis	· Phase 1 patient accrual and treatment completed Jan 2011 · Phase 1 study initiated Oct 2009

1

In addition to clinical trials, patients enrolled in the compassionate use program for PV-10 are also receiving PV-10 treatments.

Oncology (PV-10)

We believe our prescription drug candidate PV-10 may afford competitive advantage compared to currently available options for the treatment of certain types of cancer. We are developing PV-10, a sterile injectible form of rose bengal disodium (Rose Bengal), 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. We have conducted Phase 1 and Phase 2 studies of PV-10 for the treatment of metastatic melanoma, and Phase 1 studies of PV-10 for the treatment of liver and breast cancers, each of which are described in more detail below.

Metastatic Melanoma

The American Cancer Society reports that in 2010 there will have been approximately 68,000 new cases of invasive melanoma diagnosed in the U.S., leading to more than 8,700 deaths, while the World Health Organization projected that 48,000 patients died from melanoma in 2008. The National Comprehensive Cancer Network, Inc.’s Practice Guidelines in Oncology for Melanoma state "Metastatic melanoma is associated with a poor prognosis. Several chemotherapeutic agents have shown activity in patients with metastatic melanoma including dacarbazine and temozolomide as single agents as well as combination chemotherapy regimens. However, little consensus currently exists regarding standard therapy for those approximately 8,000 patients diagnosed yearly in United States with metastatic melanoma, which most likely reflects the low level of activity of all available agents."

We completed a Phase 1 study of PV-10 to assess the safety and tolerability of injection of PV-10 in the treatment of metastatic melanoma in 2007. In the study, twenty patients received injections of PV-10. The study's primary outcome measure was to determine the product's safety. The secondary outcome measure was to determine an objective response rate (ORR) of target lesions and untreated non-target lesions. A total of 114 tumors were injected and 39 bystander tumors were observed in the study. Subjects were followed for four to 27 weeks. Study treatments were well tolerated and elicited minimal side effects, the most common being mild to moderate pain at the injection site. Using the RECIST (Response Evaluation Criteria in Solid Tumors) approach, after injection with a single dose of PV-10, the following results were obtained: 20% of subjects achieved complete response (CR) of their injected tumors, 20% achieved partial response (PR), 35% achieved stable disease (SD) and 25% achieved progressive disease (PD), corresponding to an objective response (CR+PR) in 40% of subjects and local disease control (CR+PR+SD) in 75% of subjects. Among those subjects achieving an objective response of their treated tumors, 25% achieved an objective response of their untreated bystander tumors, and 100% exhibited disease control in their bystander tumors. In contrast, for those subjects failing to achieve an objective response of their treated tumors, only 8% achieved an objective response of their bystander tumors, and 92% exhibited progressive disease in their bystander tumors. These differences in response of bystander lesions as a function of response of target lesions were statistically significant and support the occurrence of a bystander effect in subjects whose target lesions have been responsive to PV-10 chemoablation.

We completed a Phase 2 study of PV-10 for intralesional injection of PV-10 in the treatment of metastatic melanoma in May, 2010. The primary outcome measure was ORR of PV-10 treated lesions for a 52 week period. The secondary outcome measures were (i) ORR of untreated bystander lesions; (ii) progression free survival (PFS) of treated lesions, (iii) duration of objective response of treated lesions, (iv) survival, and (v) assessment of systemic and locoregional adverse events during a 52-week period.

We have had our second meeting with the U.S. Food and Drug Administration (FDA) in 2011 to discuss the design of a pivotal Phase 3 randomized controlled trial suitable for SPA. During the first end of Phase 2 meeting with FDA in April 2010, we received guidance for the design of this trial.

We also met with the Australian Therapeutic Goods Administration (TGA) to review regulatory approval of PV-10 in Australia. TGA agreed to the same primary endpoint of progression free survival as was proposed to FDA during our April meeting. Use of interim data from the first half of Phase 3 study subjects, in conjunction with safety data collected in earlier studies of PV-10 for melanoma, was discussed to allow early evaluation for marketing approval for metastatic melanoma, and TGA agreed that these data should be sufficient for this review if the analysis confirmed efficacy.

Phase 2 data on visceral metastases were presented at the annual meeting of the American Society of Clinical Oncology (ASCO) in June 2010 by Dr. Sanjiv Agarwala, Chief of Medical Oncology and Hematology at St. Luke's Hospital and Health Network in Bethlehem, PA and Principal Investigator for our Phase 2 trial site at St. Luke's. Positive improvement that was observed in these remote, untreated lesions, including metastases to the lungs, liver and brain, illustrated a potential systemic effect in visceral organs to which melanoma has spread. Key conclusions included a majority of subjects exhibited a robust response in their injected lesions and response appeared to be unrelated to neither disease state nor to prior treatment history; locoregional treatment with PV-10 may elicit systemic benefit in untested visceral lesions and the overall safety and efficacy profile of PV-10 compares favorably with available and emerging options for metastatic melanoma patients. These findings are very encouraging to us as we continue on our regulatory approval path.

Dr. Agarwala later presented full Phase 2 Study data from the entire study population of 80 subjects at the Melanoma 2010 Congress in Sydney, Australia in November. The bystander effect, which appears to result from an immunologic response stimulated by PV-10 chemoablation, was noted by Dr. Agarwala, and was closely correlated with successful ablation of injected lesions. A Phase 2B clinical trial is planned to study the immunologic processes whereby PV-10 produces this systemic response. Importantly, the initial full study results for all 80 subjects enrolled in the Phase 2 study were statistically equivalent to those presented at ASCO despite the more advanced state of the second group of subjects.

We also reported progress with our Compassionate Use Program for PV-10 for non-visceral cancers. With more than 40 patients enrolled in six centers across the U.S. and Australia, the protocol enables subjects to undergo more frequent and extensive treatments of PV-10 over a longer period of time than was allowed under the protocol used for the Phase 2 trials. Its dosage is expected to serve as the blueprint for a potential Phase 3 study for metastatic melanoma. We are very thankful that these patients are benefitting from the use of PV-10 through expanded access.

We are continuing to assess whether we should conduct the Phase 3 study ourselves, partner with a larger company to co-develop PV-10 in Phase 3, and potential paths to accelerated approval in the USA and abroad.

Liver Cancer

In 2010, approximately 24,120 new cases of liver cancer were diagnosed in the U.S. and about 18,910 will die from this disease. Early detection is difficult and as a result, most cases reach an advanced metastatic stage and are unresectable. If the cancer cannot be completely removed, the disease is usually deadly within three to six months. Malignant lesions in the liver arising from primary hepatocellular carcinoma (HCC) or metastases from a wide range of cancers represent an ongoing treatment challenge for oncologists. HCC is one of the most common malignancies worldwide, and its incidence is rapidly increasing in the United States. The liver is a common site of metastases from solid tumors, particularly those arising in the gastrointestinal tract. Other tumors, such as lung and breast cancer and melanoma, also readily spread to the liver.

In 2009, we began a Phase 1 study of PV-10 to assess the safety, tolerability and pharmacokinetics of single intralesional injections of PV-10 with subjects with either recurrent hepatocellular carcinoma or cancer metastatic to the liver. In January 2011, we completed patient accrual of all subjects in the Phase 1 study. The primary outcome measure was safety, including systemic and locoregional adverse events. The secondary outcome measures were (i) lesion distribution and retention of PV-10 following injection, (ii) ORR of target and measurable bystander lesions (if present) by modified RECIST, (iii) changes in markers of hepatic function, including ALP, ALT, AST, total bilirubin and GGT, and pharmacokinetics of PV-10 in the bloodstream following intralesional injection.

Final results for PV-10 as a treatment for liver cancer are very encouraging as they show the treatment was generally well-tolerated, with substantial evidence of efficacy. We believe PV-10's ability to selectively target and destroy cancer cells without harming surrounding healthy tissue make it a potentially attractive therapy for cancers of the liver, which can be very serious and difficult to treat if they cannot be fully removed through surgery. Based upon the initial results of our PV-10 Phase 1 trial for liver cancer, and the growing confidence we have in PV-10 as a viable treatment for non-resectable liver cancer, we are currently designing a Phase 2 study.

Breast Cancer

About 207,090 new cases of invasive breast cancer were diagnosed in women in 2010 in the U.S. Breast cancer is the second leading cause of cancer death in women, exceeded only by lung cancer. Early detection of breast cancer is key, and as a result, the latest figures for five year survival rates with stage II breast cancer are 88% for stage IIA and 76% for stage IIB. Treatment for this stage breast cancer is typically surgery and chemotherapy. We plan to pursue

development of PV-10 as a neo-adjuvant to surgery on the basis of a tissue sparing endpoint.

In 2005, we began a Phase 1 study of PV-10 to assess the safety and tolerability of injections of PV-10 into recurrent breast carcinoma. We completed the Phase 1 study in 2008. The primary outcome measure was systemic and locoregional adverse experience. The secondary outcome measures were (i) histopathologic response of PV-10 injected lesions and (ii) wound healing of PV-10 injected lesions.

We are very pleased with the results of this Phase 1 clinical trial, a classic ascending dose study. Its goals were to determine the safety of the treatment and the appropriate dosage. We have also wanted to show that PV-10 has multi-indication potential. We succeeded in meeting these goals. We are now in a position for a Phase 2 study in recurrent breast carcinoma with our lead oncology drug product candidate PV-10.

Other Indications

The compassionate use program for PV-10 is only available for cancer indications that do not involve treatment of visceral organs and are not subject to enrollment in ongoing clinical trials. These indications include certain breast cancers, basal cell carcinoma, squamous cell carcinoma, certain head and neck cancers and melanoma. Compassionate use programs provide patients with access to experimental therapeutics prior to FDA approval.

The protocol for the compassionate use program enables subjects to undergo more frequent and extensive treatments of PV-10 over a longer period of time than was allowed under the protocol used for the Phase 2 trial of PV-10. Based on the success of the compassionate use program, its dose regimen is expected to serve as the blueprint for a potential Phase 3 study for metastatic melanoma. The majority of patients enrolled in the program have been treated for melanoma, with one patient treated for both melanoma and recurrent squamous cell carcinoma

Dermatology (PH-10)

Our prescription drug candidate PH-10 is an aqueous hydrogel formulation of Rose Bengal for topical administration to the skin. We are developing PH-10 for the treatment of cutaneous skin disorders, specifically psoriasis and atopic dermatitis, and we believe that PH-10 may be successful in treating other skin diseases. We believe that PH-10 offers a superior treatment for psoriasis and atopic dermatitis because it selectively treats diseased tissue with negligible potential for side effects in healthy tissue.

We have been actively discussing licensing transactions with a number of potential outlicensing partners for PH-10. We believe that our Phase 2c trial of PH-10 for psoriasis will further solidify the commercial viability of PH-10 in these discussions. In July 2010, we agreed to license Numoda Capital Innovations LLC's TruPoints strategic partnering platform. TruPoints can be used to facilitate transactions with potential licensing partners for PH-10 for either psoriasis or atopic dermatitis, or both.

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. There is no known cure for the disease at this time. According to the National Institutes of Health, as many as 7.5 million Americans, or approximately 2.2 percent of the U.S. population, have psoriasis. The National Psoriasis Foundation reports that approximately 125 million people worldwide, 2 to 3 percent of the total population, have psoriasis. It also reports that total direct and indirect health care costs of psoriasis for patients exceed $11 billion annually.

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.

Our Phase 1 study for PH-10 was initiated in April 2001 to evaluate the safety of three different doses of PH-10 in separate patient segment groups. Subjects in the study each received a single dose of PH-10 followed by administration of green light on psoriatic plaques. Subjects were examined post-treatment, with a final follow-up examination at 90 days.

Our Phase 2 study of PH-10 for treatment of psoriasis was initiated in 2009 and completed in April 2010. There were 30 subjects treated in the completed Phase 2 study, and an additional six subjects were treated in an earlier study that was terminated in favor of an increased dosing frequency. Consistent with the preliminary data that we announced in December 2009, 70% of the 30 subjects enrolled in the Phase 2 clinical trial of PH-10 for psoriasis demonstrated improvement in their Psoriasis Severity Index (PSI) scores at the end of four weeks of daily treatment with PH-10. In addition, 86% of subjects reported no or only mild pruritus (itching) by week four of the trial, and no significant safety issues were noted. At the four week interval substantial improvement was observed across all standard disease assessment scores.

During 2010, we initiated a Phase 2c clinical trial of PH-10 for psoriasis. This multicenter, randomized controlled Phase 2c study is expected to enroll up to 90 subjects at four different sites, which began in December 2010. The subjects will be randomized sequentially by center to one of four treatment cohorts, and will assess efficacy and safety of topical PH-10 applied once daily to areas of mild to moderate plaque psoriasis. The primary efficacy endpoint is "treatment success," a static endpoint assessed at day 29 after initial PH-10 treatment and defined as 0 or 1 on all Psoriasis Severity Index (PSI) components and 0 or 1 on the Plaque Response scale. The primary safety endpoint is incidence of adverse experiences, including pain and dermatologic/skin toxicity (incidence, severity, frequency, duration and causality). The secondary outcome measures are (i) Psoriasis Severity Index (PSI) score changes at each visit from day 1 pre-treatment, (ii) Plaque Response score changes at each visit from day 1 pre-treatment, and (iii) Pruritus Self-Assessment score changes at each visit from day 1 pre-treatment.

The Phase 2c trial will be conducted at four sites in the U.S. including the Mount Sinai School of Medicine in New York City, Wake Research Associates in Raleigh, NC, Dermatology Specialists in Oceanside, CA and International Dermatology Research in Miami, FL. With 90 subjects, this trial is the largest dermatological trial that we have conducted to date.

The results of this study are expected to define the parameters necessary for the design of a pivotal Phase 3 trial, and will be an important milestone on the regulatory pathway leading towards commercialization. In addition, we've held discussions with a number of potential outlicensing partners, and we believe this Phase 2c trial will further solidify the commercial viability of PH-10 in these discussions.

Atopic Dermatitis

Atopic Dermatitis, the most severe and common type of eczema, is a long-term skin disease that causes dry and itchy skin, rashes on the face, inside the elbows, behind the knees, and on the hands and feet. Scratching of the afflicted skin can cause redness, swelling, cracking, weeping clear fluid, crusting, thick skin, and scaling. According to the National Eczema Association, physicians estimate that 65% of eczema patients are diagnosed in the first year of life and 90% of patients experience it before age five. Often the symptoms fade during childhood, though most will have atopic dermatitis for life. The National Eczema Association estimates that atopic dermatitis affects over 30 million Americans.

In 2008, we initiated a Phase 2 study of PH-10 for the treatment of atopic dermatitis. This Phase 2 study assessed whether topical PH-10 applied once daily to mild, moderate or severe atopic dermatitis may ameliorate inflammation of the skin when activated by ambient light. The subjects applied PH-10 daily for 28 days to skin areas affected by atopic dermatitis. The subjects were assessed weekly during the treatment period and for four weeks following the treatment period. The primary outcome measures were (i) treatment success, defined as a score of 0 to 1 at day 28, the end of the study treatment period, by the Investigator's Global Assessment (IGA) scoring system for atopic dermatitis status, and (ii) adverse experience, including pain and dermatologic/skin toxicity (incidence, severity, frequency, duration and causality) during the eight weeks following treatment.

Data from the subjects indicated that a substantial majority of subjects had improvement in the Eczema Area Severity Index (EASI) during four weeks of treatment. The treatments were generally well tolerated with no significant safety issues identified. At the four week interval substantial improvement was observed across all standard disease assessment scores.

Other Indications

We have investigated the use of PH-10 for treatment of actinic keratosis (also called solar keratosis or senile keratosis), which 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. We have previously conducted a Phase I clinical trial of PH-10 for actinic keratosis to examine the safety profile of a single treatment using topical PH-10 with green light photoactivation. No significant safety concerns were identified in the study. We have decided to prioritize further clinical development of PH-10 for treatment of psoriasis and atopic dermatitis rather than actinic keratosis at this time since the market is much larger for psoriasis and atopic dermatitis.

We have also conducted pre-clinical studies of PH-10 for use in treating severe acne vulgaris. Moderate to severe forms of the disease have proven responsive to several photodynamic regimens, and we anticipate that PH-10 can be used as an advanced treatment for this disease. Our pre-clinical studies show that the active ingredient in PH-10 readily kills bacteria associated with acne. This finding, coupled with our clinical experience in psoriasis, atopic dermatitis, and actinic keratosis, suggests that therapy with PH-10 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.

The active ingredient in PH-10 is photoactive in that it reacts to light of certain wavelengths thereby potentially increasing its therapeutic effects. We believe that photodynamic treatment regimens can deliver a higher therapeutic effect at lower dosages of active ingredient, thus minimizing potential side effects including damage to nearby healthy tissues. PH-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, in the past we have investigated PH-10 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.

Over-the-Counter Pharmaceuticals

We have designated our subsidiary that holds our OTC products, GloveAid and Pure-ific, Pure-Stick, Pure N Clear as non-core. The potential further development and licensure of our OTC products would likely be facilitated by selling a majority stake of the underlying assets of the non-core subsidiary holding the OTC products. This transaction would likely be accomplished through a non-core spin-out process, which would enable the non-core subsidiary to become a separate publicly held company. The new public entity could then raise funds without diluting the ownership of the then current shareholders of the Company.

GloveAid

Personnel in many occupations and industries now use disposable gloves daily in the performance of their jobs, including airport security personnel, food handling and preparation personnel, health care workers such as hospital and blood bank personnel, laboratory researchers, police, fire and emergency response personnel, postal and package delivery handlers and sorters, and sanitation workers.

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.

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 six 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 stores) 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 and 2006, most of our sales were generated from customers accessing our website for Pure-ific and making purchases online. We discontinued our proof-of-concept program in November 2006 and have, therefore, ceased selling our OTC products. The Company now intends to license the Pure-ific product. The Company has been discussing this strategy with interested groups. Additionally, the Company also intends to sell a majority stake in the underlying assets via a non-core spin-out transaction.

Acne

Our acne products Pure-Stick and Pure N Clear work by decreasing the production of fats, oils and sweat that create an environment conducive to unchecked growth of bacteria. Secondly, the products also act to reduce the number bacteria already present. Pure-Stick and Pure N Clear represent new formulations of proven, safe ingredients that achieve both steps required to successfully treat acne. Since Pure-Stick and Pure N Clear are applied topically to affected areas there are no safety concerns with healthy skin. The unique combinations have allowed the Company to secure patent protection for these products.

Medical Devices

We have medical device technologies that we believe may address two major markets:

- cosmetic treatments, such as reduction of wrinkles and elimination of spider veins and other cosmetic blemishes; and

- therapeutic uses, including photoactivation of PH-10 other prescription drugs and non-surgical destruction of certain skin cancers.

We expect to further develop medical devices through partnerships with, or selling our assets to, third-party device manufacturers or, if appropriate opportunities arise, through acquisition of one or more device manufacturers. Additionally, the Company also intends to sell a majority stake in the underlying assets via a non-core spin-out transaction.

Photoactivation

Our clinical tests of PH-10 for dermatology have in the past 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 PH-10. 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.

Laser-Based 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 believe that our extremely successful results could be extrapolated to treatment of primary melanomas of the skin, which have an incidence of over 60,000 new cases annually in the U.S. and a 6% 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, or selling our assets to, 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.

Research and development costs totaling $8,417,303 for 2010 included payroll of $6,618,532, consulting and contract labor of $1,095,793, lab supplies and pharmaceutical preparations of $235,153, legal of $300,964, insurance of $90,314, rent and utilities of $67,692, and depreciation expense of $8,855. Research and development costs totaling $4,909,414 for 2009 included payroll of $2,860,116, consulting and contract labor of $1,367,422, lab supplies and pharmaceutical preparations of $281,833, legal of $209,709, insurance of $125,295, rent and utilities of $55,685, and depreciation expense of $9,354.

Production

We have determined that the most efficient use of our capital in further developing our OTC products is to license the products. The Company has been discussing this strategy with interested groups. Additionally, the Company also intends to sell a majority stake in the underlying assets via a non-core spin-out transaction.

Sales

We have not had any significant sales of any of our OTC products, though we commenced limited sales of Pure-ific, our antibacterial hand spray in 2004 through 2006 in a proof-of-concept program. We discontinued our proof-of-concept program in 2006 and have, therefore, ceased selling our OTC products. 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, partnership and asset sale 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. All patents material to an understanding of the Company are included and a cross reference to a discussion that explains the patent technologies and products is identified for each patent in the following table:

U.S. Patent No	Title and Cross Reference	Issue Date	Expiration Date
5,829,448	Method for improved selectivity in activation of molecular agents; see discussion under Medical Devices in Description of Business	November 3, 1998	October 30, 2016
5,832,931	Method for improved selectivity in photo-activation and detection of diagnostic agents; see discussion under Medical Devices in Description of Business	November 10, 1998	October 30, 2016
5,998,597	Method for improved selectivity in activation of molecular agents; see discussion under Medical Devices in Description of Business	December 7, 1999	October 30, 2016
6,042,603	Method for improved selectivity in photo-activation of molecular agents; see discussion under Medical Devices in Description of Business	March 28, 2000	October 30, 2016
6,331,286	Methods for high energy phototherapeutics; see discussion under Oncology in Description of Business	December 18, 2001	December 21, 2018
6,451,597	Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	September 17, 2002	April 6, 2020
6,468,777	Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	October 22, 2002	April 6, 2020
6,493,570	Method for improved imaging and photodynamic therapy; see discussion under Oncology in Description of Business	December 10, 2002	December 10, 2019
6,495,360	Method for enhanced protein stabilization for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	December 17, 2002	April 6, 2020
6,519,076	Methods and apparatus for optical imaging; see discussion under Medical Devices in Description of Business	February 11, 2003	October 30, 2016

6,525,862	Methods and apparatus for optical imaging; see discussion under Medical Devices in Description of Business	February 25, 2003	October 30, 2016
6,541,223	Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	April 1, 2003	April 6, 2020
6,986,740	Ultrasound contrast using halogenated xanthenes; see discussion under Oncology in Description of Business	January 17, 2006	September 9, 2023
6,991,776	Improved intracorporeal medicaments for high energy phototherapeutic treatment of disease; see discussion under Oncology in Description of Business	January 31, 2006	May 5, 2023
7,036,516	Treatment of pigmented tissues using optical energy; see discussion under Medical Devices in Description of Business	May 2, 2006	January 28, 2020
7,201,914	Combination antiperspirant and antimicrobial compositions; see discussion under Over-the-Counter Pharmaceuticals in Description of Business	April 10, 2007	May 15, 2024
7,338,652	Diagnostic Agents for Positron Emission Imaging; see discussion under Oncology in Description of Business	March 4, 2008	September 25, 2025
7,346,387	Improved Selectivity in Photo-Activation and Detection of Molecular Diagnostic Agents; see discussion under Medical Devices in Description of Business	March 18, 2008	October 30, 2016
7,353,829	Improved Methods and Apparatus For Multi-Photon Photo-Activation of Therapeutic Agents; see discussion under Medical Devices in Description of Business	April 8, 2008	April 23, 2020
7,384,623	A Radiosensitizer Agent comprising Tetrabromoerythrosin; see discussion under Oncology in Description of Business	June 10, 2008	August 25, 2019
7,390,668	Intracorporeal photodynamic medicaments for photodynamic treatment containing a halogenated xanthene or derivative; see discussion under Dermatology in Description of Business	June 24, 2008	March 6, 2021

7,402,299	Intracorporeal photodynamic medicaments for photodynamic treatment containing a halogenated xanthene or derivative; see discussion under Dermatology in Description of Business	July 22, 2008	October 2, 2025
7,427,389	Diagnostic Agents for Positron Emission Imaging; see discussion under Oncology in Description of Business	September 23, 2008	July 7, 2026
7,648,695	Improved Medicaments for chemotherapeutic treatment of disease; see discussion under Oncology in Description of Business	January 19, 2010	July 6, 2021
7,864,047	Improved intracorporeal medicaments for photodynamic treatment of disease; see discussion under Dermatology in Description of Business	January 4, 2011	October 30, 2016

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: GloveAid TM and Pure-ific TM (including Pure-ific TM and Pure-ific TM Kids). We also own the registered trademark PulseView ® . 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 which is still in effect. 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 cannot assure you 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.

The Company has received no "progress payments" in relation to its Material Transfer Agreement with SPAH. Progress payments could potentially total $50,000 for the first cell line for which SPAH uses our technology and $25,000 for each use of the same technology thereafter. We do not know how many cell lines SPAH may have and we currently have no indication from SPAH that it intends to use any of our technologies in the foreseeable future.

Additionally, the Company also intends to sell a majority stake in these underlying assets via a non-core spin-out transaction.

Competition

In general, the pharmaceutical and biotechnology industries are 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 and biotechnology 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.

9

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. Eventually, we believe that we will be acquired.

We also have a number of market areas in common with traditional skincare cosmetics companies, but in contrast to these companies, our products are based on unique, proprietary formulations and approaches. For example, we are unaware of any products in our targeted OTC skincare markets that are similar to our Pure-ific product. 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 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:

- Using chemicals and combinations already allowed by the FDA;
- Using drugs that have been previously approved by the FDA and that have a long history of safe use; and
- Using chemical compounds with known safety profiles

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:

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

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 previously 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 have sold. The FDA can, however, require us to stop selling our product if we fail to comply with the rules applicable to our OTC products.

Employees

We currently employ four persons, all of whom are full-time employees. We currently engage four full-time consultants, including a regulatory affairs consultant, a contract research associate, an analytical chemist, and an information technology consultant.

Our executive officers and directors are:

H. Craig Dees, Ph.D. , 59, has served as our Chief Executive Officer and as a member of our board of directors since we acquired PPI, a privately held Tennessee corporation 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 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 earned a Ph.D. in Molecular Virology from the University of Wisconsin–Madison in 1984.

Timothy C. Scott, Ph.D. , 52, 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 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 Oak Ridge National Laboratory. Dr. Scott earned a Ph.D. in Chemical Engineering from the University of Wisconsin–Madison in 1985.

Eric A. Wachter, Ph.D. , 48, has served as our Executive 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 Oak Ridge National Laboratory. He earned a Ph.D. in Chemistry from the University of Wisconsin–Madison in 1988.

Peter R. Culpepper , 51, was appointed to serve as our Chief Financial Officer in February 2004 and is also our Chief Operating Officer. 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 a Masters in Business Administration in Finance from the University of Maryland–College Park in 1992. He earned an AAS in Accounting from the Northern Virginia Community College–Annandale, Virginia in 1985. He earned a B.A. in Philosophy from the College of William and Mary–Williamsburg, Virginia in 1982. He is a licensed Certified Public Accountant in both Tennessee and Maryland.

Stuart Fuchs , 64, has served as a member of our board of directors since January 23, 2003. He is a co-founder and has served as a managing principal of Gryffindor Capital Partners, LLC, a Chicago-based venture capital firm, since January 2000. Before joining Gryffindor, he was a founding stockholder of several biotech companies, including Angiogen LLC (since 1998), which develops combinations of drugs to stimulate in vivo production of factors that inhibit the growth of blood vessels in tumors, and Nace Pharma LLC (since 1996), which develops drugs that employ novel drug delivery technologies. Through Nace Resources Inc., a Delaware corporation providing strategic and financial advice to companies in the technology sector, Mr. Fuchs has formed or participated in groups of investors on behalf of several companies, including Abiant Inc., Celsion Corp. and Photogen. Before founding Nace Resources Inc., he served for 19 years as an investment banker with Goldman, Sachs & Co., where he co-managed the firm's

public finance activities for the Midwest region. Before joining Goldman, Sachs & Co., Mr. Fuchs was a lawyer in private practice with Barrett Smith Schapiro & Simon in New York. Mr. Fuchs holds an A.B. degree from Harvard College and a J.D. from Harvard Law School and is a member of the Association of the Bar of the City of New York.

Kelly M. McMasters M.D., Ph.D. , 50, has served as a member of our board of directors since June 9, 2008. Additionally, Dr. McMasters serves as chairman of our scientific advisory board. Dr. McMasters received his undergraduate training at Colgate University prior to completing the MD/PhD program at the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School and Rutgers University. He then completed the residency program in General Surgery at the University of Louisville, and a fellowship in Surgical Oncology at M.D. Anderson Cancer Center in Houston. He is currently the Sam and Lolita Weakley Professor of Surgical Oncology at the University of Louisville in Kentucky, a position he has held since 1996. Since 2005, he has chaired the Department of Surgery at the University of Louisville and also has been Chief of Surgery at University of Louisville Hospital. Since 2000, he has also been Director of the Multidisciplinary Melanoma Clinic of the James Graham Brown Cancer Center at the University of Louisville. His is an active member of the surgery staff at the University of Louisville Hospital, Norton Hospital and Jewish Hospital in Louisville. He is on the editorial boards of the Annals of Surgical Oncology, Cancer Therapy and the Journal of Clinical Oncology as well as an ad hoc reviewer for 9 other publications. He holds several honors, chief among them is "Physician of the Year" awarded by the Kentucky Chapter of the American Cancer Society. He is the author and principal investigator (PI) of the Sunbelt Melanoma Trial, a multi-institutional study involving 3500 patients from 79 institutions across North America and one of the largest prospective melanoma studies ever performed. He has been a PI, Co-PI or local PI in over thirty clinical trials ranging from Phase 1 to Phase 3. For the past 12 years he has also directed a basic and translational science laboratory studying adenovirus-mediated cancer gene therapy funded by the American Cancer Society and the National Institutes of Health (NIH).

Equity Financing During 2010

During 2010, we completed several equity financings, which together with exercises of existing warrants and stock options reasonably assured us that our capital resources will be sufficient to fund our current and planned operations until 2013. During 2010, we received net proceeds of $18,580,350 through equity offerings and exercises of existing warrants to purchase our common stock as described below.

In March 2010 and April 2010, we completed private offerings pursuant to which we sold a total of 13,283,324 units, at a purchase price of $0.75 per unit, each unit consisting of one share of 8% convertible preferred stock, par value $.001 per share and a warrant to purchase one-half share of common stock, par value $.001 per share, totaling 6,641,654 warrants with an exercise price of $1.00 per share of common stock. Our net proceeds in the March and April 2010 unit offerings were $8,908,131.

During 2010, we completed private offerings under Regulation D and Regulation S pursuant to which we sold a total of 10,727,067 shares of common stock and 600,000 warrants to purchase common stock for aggregate net proceeds of $6,766,239.

In December 2010, we completed a registered direct offering with Lincoln Park Capital Fund, LLC, pursuant to which Lincoln Park purchased 1,000,000 shares of our common stock together with a warrant to purchase an additional 500,000 shares of our common stock for an aggregate purchase price of $1,000,000. In addition to the foregoing investment, under the purchase agreement we may, in our sole discretion, direct Lincoln Park to purchase up to an additional $30,000,000 of our common stock over the term of the purchase agreement. However, under a securities purchase agreement that we entered into in January 2011, which is described in the subsequent event note to our financial statements, we have agreed not to draw down on the Lincoln Park purchase agreement until on or after November 16, 2011.

During 2010, we received proceeds of $2,905,980 from the exercise of warrants and stock options.

Available Information

Our website is located at www.pvct.com. We make available free of charge through this website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed with or furnished to the Securities and Exchange Commission (SEC) pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC.

ITEM 1A. RISK FACTORS.

Our business and its future performance may be affected by various factors, the most significant of which are discussed below.

We are a development stage company, have no prescription drug products approved for commercial sale, have incurred substantial losses, and expect to incur substantial losses and negative operating cash flow for the foreseeable future.

Our company is a development stage company that has no prescription drug products approved for commercial sale. We have never generated any substantial revenues and may never achieve substantial revenues or profitability. As of December 31, 2010, we have incurred net losses of $86.4 million in the aggregate since inception in January 2002. We expect to incur substantial losses and negative operating cash flow for the foreseeable future. We may never achieve or maintain profitability, even if we succeed in developing and commercializing one or more of our prescription drug candidates, OTC products, or medical device technologies. We also expect to continue to incur significant operating expenditures and anticipate that our operating and capital expenses may increase substantially in the foreseeable future as we:

- continue to develop and seek regulatory approval for our prescription drug candidates PV-10 and PH-10;
- seek licensure of PV-10, PH-10, our OTC products, and our medical device technologies;
- further develop our medical device technologies;
- implement additional internal systems and infrastructure; and
- hire additional personnel.

We also expect to experience negative operating cash flow for the foreseeable future as we fund our operating losses and any future capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

All of our existing prescription drug candidates are in early stages of development. It may be several years, if ever, until we have a prescription drug product available for commercial resale. If we do not successfully develop and license or commercialize our prescription drug candidates, or sell or license our OTC products or medical device technologies, we will not achieve revenues or profitability in the foreseeable future, if at all. If we are unable to generate revenues or achieve profitability, we may be unable to continue our operations.

We may need additional capital to conduct our operations and commercialize and/or further develop our prescription drug candidates in 2013 and beyond, 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 until 2013. However, we may need additional capital in 2013 and beyond as we continue to develop and seek commercialization of our prescription drug candidates. We intend to proceed as rapidly as possible with licensure of PH-10 on the basis of our Phase 2 atopic dermatitis and psoriasis results, which were completed in 2010. We potentially may license PV-10 depending on the timing for the optimal deal structure for our stockholders. We intend to also proceed as rapidly as possible with the sale or licensure of our OTC products and medical device technologies. Although we believe that there is a reasonable basis for our expectation that we will become profitable due to both the

licensure of PH-10 and the sale or licensure of our OTC products and medical device technologies, we cannot assure you that we will be able to achieve, or maintain, a level of profitability sufficient to meet our operating expenses.

We have based our estimate of capital needs 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 or debt 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 stockholders. 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 products, product candidates, and technologies 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.

Our prescription drug candidates are at an early stage of development and may never obtain U.S. or international regulatory approvals required for us to commercialize our prescription drug candidates.

We will need approval of the United States Food and Drug Administration, which we refer to as the "FDA," to commercialize our prescription drug candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our prescription drug candidates in those jurisdictions.

We are continuing to pursue clinical development of our most advanced prescription drug candidates, PV-10 and PH-10, for use as treatments for specific conditions. The continued and further development of these prescription drug candidates will require significant additional research, formulation and manufacture development, and pre-clinical and extensive clinical testing prior to their regulatory approval and commercialization. Pre-clinical and clinical studies of our prescription drug candidates 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:

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

Satisfaction of the FDA’s regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

We do not expect any prescription drug and medical device candidates that we are developing to be commercially available for 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.

Even if we comply with all FDA requests, we cannot be sure that we will ever obtain regulatory clearance for any of our prescription drug or medical device product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above.

Clinical trials are very expensive, time consuming and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that current or future clinical trials of our prescription drug candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our submissions or the conduct of these trials.

The results of our clinical trials may not support our claims concerning our prescription drug candidates.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims concerning our prescription drug candidates. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and nonclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans or effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay our ability to commercialize our product candidates and generate product revenues. In addition, we anticipate that our clinical trials will involve only a small patient population. Accordingly, the results of such trials may not be indicative of future results over a larger patient population.

Physicians and patients may not accept and use our prescription drug candidates.

Even if the FDA approves our prescription drug candidates, physicians and patients may not accept and use them. Acceptance and use of our prescription drug products will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our prescription drug products;
- cost-effectiveness of our prescription drug products relative to competing products;
- availability of reimbursement for our prescription drug products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales or licensure of our prescription drug candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

We have no sales, marketing or distribution capabilities for our prescription drug candidates or our OTC products and medical device technologies.

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our prescription drug candidates or our OTC products and medical device technologies. Our future success depends, in part, on our ability to enter into and maintain such collaborative relationships, the collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products. We intend to proceed as rapidly as possible with licensure of PH-10 on the basis of our Phase 2 atopic dermatitis and psoriasis results, which are in process of being completed. We have determined that that the most efficient use of our capital in further developing our OTC products is to license the products. There can be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product in the United States or overseas.

We cannot be sure that our OTC products or medical device technologies will be licensed or sold in the marketplace.

In order for our OTC products to become commercially successful and our medical device technologies to be further developed, we must license or sell those products and technologies. We have been discussing this strategy with interested groups, though we cannot be sure that we will be successful in licensing or selling such products or technologies.

Competition in the prescription pharmaceutical and biotechnology industries 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 and medical device candidates 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:

- research and development;
- manufacturing;
- preclinical and clinical testing;
- obtaining regulatory approvals; and
- 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 may also 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:

- product efficacy and safety;
- the timing and scope of regulatory consents;
- availability of resources;
- reimbursement coverage;
- price; and

- patent position, including potentially dominant patent positions of others.

Since our prescription candidates PV-10 and PH-10 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 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 subject us 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.

We also rely upon trade secrets, unpatented proprietary know-how, and continuing technological innovation 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, results of operations, and cash flows.

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

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

- H. Craig Dees, Ph.D., our Chief Executive Officer;
- Timothy C. Scott, Ph.D., our President;
- Eric A. Wachter, Ph.D. our Executive Vice President - Pharmaceuticals; and
- Peter R. Culpepper, CPA, our Chief Financial Officer and Chief Operating 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 our prescription drug and medical device candidates and our OTC products. 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 employees if any of our key employees should choose to leave.

Because we have only four 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:

-

Researching diseases and possible therapies in the areas of dermatology and skin care, oncology, and biotechnology;

- Developing our prescription drug and medical device candidates and OTC products based on our research;
- Marketing and selling developed products;
- Obtaining additional capital to finance research, development, production, and marketing of our products; and
- Managing our business as it grows.

As discussed above, we currently have only four employees, all of whom are full-time employees. The greatest burden of succeeding in the above areas, therefore, falls on Drs. Dees, Scott, Wachter, and Mr. Culpepper. Focusing on any one of these areas may divert their attention from our other areas of concern and could affect our ability to manage other aspects of our business. We cannot assure you that our management will be able to succeed in all of these areas or, even if we do so succeed, that our business will be successful as a result. We anticipate adding an additional regulatory affairs officer on a consulting basis within several months. 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.

The market price of our common stock has been highly volatile due to several factors that will continue to affect the price of our common stock.

Our common stock has traded as low as $0.68 per share and as high as $1.76 per share during the period beginning on January 1, 2009 and ending on December 31, 2010. We believe that our common stock is subject to wide price fluctuations because of several factors, including:

- absence of meaningful earnings and ongoing need for external financing;
- 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;
- general volatility of the stock market and the market prices of other publicly-traded companies; and
- investor sentiment regarding equity markets generally, including public perception of corporate ethics and governance and the accuracy and transparency of financial reporting.

Financings that may be available to us under current market conditions frequently involve sales at prices below the prices at which our common stock trades on the OTC Bulletin Board, as well as the issuance of warrants or convertible equity or 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. The current economic downturn has made the financings available to development-stage companies like us more dilutive in nature than they would otherwise be.

Any agreement to sell, or convert debt or equity securities into, our 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 our 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.

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:

- broker-dealers must deliver, prior to the transaction a disclosure schedule prepared by the SEC relating to the penny stock market;
- broker-dealers must disclose the commissions payable to the broker-dealer and its registered representative;
- broker-dealers must disclose current quotations for the securities;
- 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
- a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all penny stocks held in the customer’s account and information on the limited market in penny stocks.

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

Future sales by our stockholders may adversely affect our stock price and our ability to raise funds in new stock offerings.

Sales of our common stock in the public market following any prospective offering could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable. The current economic downturn has made the financings available to development-stage companies like us more dilutive in nature than they would otherwise be.

We currently intend to retain all of our future earnings rather than pay a cash dividend.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not required.

ITEM 2. PROPERTIES.

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 $4,500 per month, and the lease is on a month-to-month basis. We believe that these offices generally are adequate for our needs currently and in the immediate future.

ITEM 3. LEGAL PROCEEDINGS.

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. [REMOVED AND RESERVED].

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

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 sale prices of our common stock for the periods indicated since January 1, 2009:

	High	Low
2009		
First Quarter (January 1 to March 31)	$ 1.04	$ 0.80
Second Quarter (April 1 to June 30)	$ 1.33	$ 0.81
Third Quarter (July 1 to September 30)	$ 1.14	$ 0.85
Fourth Quarter (October 1 to December 31)	$ 1.14	$ 0.68
2010		
First Quarter (January 1 to March 31)	$ 1.76	$ 0.80
Second Quarter (April 1 to June 30)	$ 1.60	$ 1.08
Third Quarter (July 1 to September 30)	$ 1.19	$ 0.89
Fourth Quarter (October 1 to December 31)	$ 1.32	$ 0.88

The closing price for our common stock on March 7, 2011 was $0.96. High and low sale price information was obtained from data provided by Yahoo! Inc.

As of March 7, 2011, we had 1,891 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.

In March and April 2010, we issued 13,283,324 shares of our 8% convertible preferred stock, par value $.001 per share, of which 4,929,997 shares were outstanding on March 7, 2011. The holders of shares of the 8% convertible preferred stock are entitled to dividends of 8% per year, payable quarterly in cash or, at our discretion, shares of our common stock based on the volume-weighted average price of our stock for the fifteen trading days prior to the dividend payment date. During 2010, we made all dividend payments on the 8% convertible preferred stock in shares of our common stock, and we expect to continue to pay such dividends in our common stock rather than cash.

Recent Sales of Unregistered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA.

Not required.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

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 in this report. Historical results and percentage relationships set forth in the statement of operations, including trends which might appear, are not necessarily indicative of future operations.

Critical Accounting Policies

Long-Lived Assets

We review the carrying values of our long-lived assets for possible impairment whenever an event or change in circumstances indicates that the carrying amount of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair value less cost to sell. Management has determined there to be no impairment.

Patent Costs

Internal patent costs are expensed in the period incurred. Patents purchased are capitalized and amortized over their remaining lives, which range from 6-11 years. Annual amortization of the patents is expected to approximate $671,000 for each of the next five years.

Stock-Based Compensation

The compensation cost relating to share-based payment transactions is measured based on the fair value of the equity or liability instruments issued and is expensed on a straight-line basis. For purposes of estimating the fair value of each stock option, on the date of grant, we utilize the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of the company’s common stock (as determined by reviewing its historical public market closing prices). Because our employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management’s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

Warrants to non-employees are generally vested and nonforfeitable upon the date of the grant. Accordingly fair value is determined on the grant date.

Research and Development

Research and development costs are charged to expense when incurred. An allocation of payroll expenses to research and development is made based on a percentage estimate of time spent. The research and development costs include the following: payroll, consulting and contract labor, lab supplies and pharmaceutical preparations, legal, insurance, rent and utilities, and depreciation.

Derivative Instruments

The warrants issued in conjunction with convertible preferred stock in March and April 2010 private placements include a reset provision if the Company issues additional warrants, in certain circumstances as defined in the agreement, below the exercise price of $1.00. Effective January 1, 2009, the reset provision of these warrants preclude equity accounting treatment under ASC 815 (formerly EITF 07-5). Accordingly the Company is required to record the warrants as liabilities at their fair value upon issuance and remeasure the fair value at each period end with the change in fair value recorded in the statement of operations. When the warrants are exercised or cancelled, they are reclassified to equity. The Company used the Monte-Carlo Simulation model to estimate the fair value of the warrants. Significant assumptions used at December 31, 2010 include a weighted average term of 4.23 years, a 5% probability that the warrant exercise price would be reset, a volatility range between 69.7% and 71.9% and a risk free interest rate

range between 1.3% and 2.6%.

Fair Value of Financial Instruments

The fair value of derivative instruments is determined by management with the assistance of an independent third party valuation specialist. Certain derivatives with limited market activity are valued using externally developed models that consider unobservable market parameters.

Contractual Obligations - Leases

We lease office and laboratory space in Knoxville, Tennessee, on a month-to-month basis.

Capital Structure

Our ability to continue as a going concern is reasonably assured due to our financing completed during 2010 and thus far in 2011 and warrants and stock options exercised during 2010. Given our current rate of expenditures, we do not need to raise additional capital unless we commercialize PV-10 on our own to treat metastatic melanoma. Additionally, our existing funds are sufficient to meet minimal necessary expenses until 2013.

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 a licensure of our dermatology drug product candidate (PH-10) on the basis of our Phase 2 atopic dermatitis and psoriasis results, which are in process of being completed. We intend to also proceed as rapidly as possible with a majority stake asset sale and subsequent licensure of our OTC products that can be sold with a minimum of regulatory compliance and with the further development of revenue sources through a majority stake asset sale and subsequent licensing of our existing medical device, imaging, and biotech intellectual property portfolio. Although we believe that there is a reasonable basis for our expectation that we will become profitable due to both the licensure of PH-10 and the asset sale of a majority stake via a spin-out transaction of the wholly-owned subsidiaries that contain the non-core assets and subsequent licensure of our non-core 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 four employees during the immediate future, but we have added two additional consultants to the two we already had, and anticipate adding two more consultants 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

We believe that our prescription drug candidates PV-10 and PH-10 provide us with two products in multiple indications, which have been shown in clinical trials to be safe to treat serious cancers and diseases of the skin. We continue to develop clinical trials for these products to show their safety and efficacy, which we believe will be shown based on data in previous studies. Together with our OTC products, medical device, biotech and other non-core technologies, which we intend to sell or license in the future, we believe this combination represents the foundation for maximizing shareholder value this year and next.

Comparison of the Years Ended December 31, 2010 and 2009

Revenues

We had no revenue during the years ended 2010 and 2009.

Research and development

Research and development costs totaling $8,417,303 for 2010 included payroll of $6,618,532, consulting and contract labor of $1,095,793, lab supplies and pharmaceutical preparations of $235,153, legal of $300,964, insurance of $90,314, rent and utilities of $67,692, and depreciation expense of $8,855. Research and development costs totaling $4,909,414 for 2009 included payroll of $2,860,116, consulting and contract labor of $1,367,422, lab supplies and pharmaceutical preparations of $281,833, legal of $209,709, insurance of $125,295, rent and utilities of $55,685, and depreciation expense of $9,354.

The increase in payroll in 2010 over 2009 is primarily due to increased bonuses of approximately $2,000,000 and increased stock option expense of approximately $1,800,000, both of which increased due to the significant progress made in the clinical development program for both our oncology and dermatology drug product candidates. The decrease in consulting and contract labor in 2010 versus 2009 is primarily due to receipt of a grant for approximately $244,000 under the Qualifying Therapeutic Discovery Project Program.

The table below summarizes our projects, the actual costs for each period shown, and the total costs incurred to date.

Projects	Actual Cost for 2010	Actual Cost for 2009	Total Costs Incurred To Date
Melanoma	$ -0-	$ 593,000	$ 3,018,000
Breast/Other	$ -0-	$ -0-	$ 675,000
Liver	$ 110,000	$ 6,000	$ 616,000
Psoriasis/Atopic Dermatitis	$ -0-	$ 178,000	$ 1,678,000
Payroll	$ 6,619,000	$ 2,860,000	
Indirect costs	$ 1,688,000	$ 1,272,000	
Totals	$ 8,417,000	$ 4,909,000	

General and administrative

General and administrative expenses increased by $4,858,929 for 2010 to $11,604,526 from $6,745,597 in 2009. The increase is primarily due to increased bonuses and 401K expenses of approximately $2,100,000 and increased stock option expense of approximately $2,000,000, both of which increased due to the significant progress made in the clinical development program for both our oncology and dermatology drug product candidates, as well as increased investor relations expense of approximately $700,000 which increased due to the expanded programs to improve investor awareness and visibility of the Company's clinical progress.

Investment income

Investment income decreased by $2,615 in 2010 to $1,202 from $3,817 in 2009.

Cash Flow

Our cash and cash equivalents were $8,086,200 at December 31, 2010, compared with $3,237,178 at December 31, 2009. The increase of approximately $4,849,000 was due primarily to cash of $18,580,350 provided from sales of equity securities and the exercises of warrants and stock options during the year ended December 31, 2010, which was exceeded cash used in operating activities.

At our current cash expenditure rate, our cash and cash equivalents will be sufficient to meet our current and planned needs until 2013 without additional cash inflows from the exercise of existing warrants, stock options, or sales of equity securities. We have enough cash on hand to fund operations until 2013 with the cash on hand at December 31, 2010 as well as through financing completed thus far in 2011.

We are seeking to improve our cash flow through both the licensure of PH-10 on the basis of our Phase 2 atopic dermatitis and psoriasis results, and the majority stake asset sale and licensure of our OTC products as well as other non-core assets. However, we cannot assure you that we will be successful in either licensing PH-10 or selling a majority stake of the OTC and other non-core assets via a spin-out transaction and licensing our existing non-core products. Moreover, even if we are successful in improving our current cash flow position, we nonetheless plan to seek additional funds to meet our long-term requirements in 2013 and beyond. We anticipate that these funds will otherwise 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 and cash equivalents is currently sufficient to meet our short-term operating needs. Excess cash will be used to finance any additional phases in clinical development of our pharmaceutical products that we may decide to undertake ourselves versus with a partner. We anticipate that any required funds for our operating and development needs in 2013 and beyond will come from the proceeds of public or private sales of equity or debt securities or the exercise of existing warrants and stock options outstanding. 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.

Recent Accounting Pronouncements

In January 2010, the FASB issued FASB ASU 2010-06, which amends the disclosure requirements relating to recurring and nonrecurring fair value measurements. New disclosures are required about transfers into and out of the

Levels 1 and 2 fair value hierarchy and separate disclosures about purchases, sales, issuances and settlements relating to Level 3 measurements. This ASU also requires an entity to present information about purchases, sales, issuances and settlements for significant unobservable inputs on a gross basis rather than as a net number. This ASU was effective for us with the reporting period beginning January 1, 2010, except for the disclosures on the roll-forward activities for Level 3 fair value measurements, which will become effective for us with the reporting period beginning January 1, 2011. The adoption of this ASU had no impact on our financial position and results of operations, as it only requires additional disclosures.

In April 2010, the FASB issued ASU No. 2010-17, Revenue Recognition — Milestone Method (ASU 2010-017). ASU 2010-017 provides guidance in applying the milestone method of revenue recognition to research or development arrangements. Under this guidance, management may recognize revenue, contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved only if the milestone meets all the criteria within the guidance to be considered substantive. This ASU is effective on a prospective basis for research and development milestones achieved in fiscal years beginning on or after June 15, 2010, which for us means fiscal 2011. Early adoption is permitted; however, we have elected to implement ASU 2010-17 prospectively and, as a result, the effect of this guidance will be limited to future transactions. We do not expect adoption of this standard to have a material impact on our financial position or results of operations as we have no material research and development arrangements which will be accounted for under the milestone method.

In December 2010, the FASB issued ASU No. 2010-027, Fees Paid to the Federal Government by Pharmaceutical Manufacturers (ASU 2010-027). ASU 2010-027 provides guidance concerning the recognition and classification of the new annual fee payable by branded prescription drug manufacturers and importers on branded prescription drugs, which was mandated under the health care reform legislation enacted in the U.S. in March 2010. Under this new accounting standard, the annual fee would be presented as a component of operating expenses and recognized over the calendar year such fees are payable using a straight-line method of allocation unless another method better allocates the fee over the calendar year. This ASU is effective for calendar years beginning on or after December 31, 2010, when the fee initially becomes effective, which for us is fiscal 2011. As this standard relates only to classification, the adoption of this accounting standard will not have an impact on our financial position or results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements required by this Item are included as a separate section of this report commencing on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Act)) were not effective as of December 31, 2010, based on the evaluation of these controls and procedures required by Rule 13a-15(b) or 15d-15(b) of the Act.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance regarding the preparation and fair presentation of published financial statements in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation in accordance with generally accepted accounting principles. Based on its assessment, management concluded that our internal control over financial reporting at December 31, 2010 was not effective.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2010, using the criteria set forth in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Based on that assessment, we identified a material weakness in our internal controls. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness regarding

management’s lack of expertise in accounting for complex financial instruments has been identified by management. Specifically, the Company did not properly account for the issuance of certain warrants in accordance with Accounting Standards Codification 815-40-15 "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity’s Own Stock" in its Quarterly filings in 2010. Accordingly, we have restated the previously issued 2010 Quarterly financial statements. See Note 12 to the 2010 consolidated financial statements for a full discussion of the effects of this restatement. Subsequent to December 31, 2010, to remediate the material weakness, management hired a consultant to help them analyze and account for complex financial instruments.

Our independent registered public accounting firm has issued an audit report on the effectiveness of our internal control over financial reporting. That report is included herein.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the fourth quarter of 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Provectus Pharmaceuticals, Inc.
Knoxville, Tennessee

We have audited Provectus Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Provectus Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Item 9A, Management's Report on Internal Control Over Financial Reporting". Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness regarding management's failure to design and maintain controls over accounting for complex financial instruments has been identified and described in management's assessment. Specifically, the Company did not properly account for the issuance of certain warrants in accordance with Accounting Standards Codification 815-40-15 "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock". This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2010 consolidated financial statements, and this report does not affect our report dated March 16, 2011 on those consolidated financial statements.

In our opinion, Provectus Pharmaceuticals, Inc. did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

We do not express an opinion or any other form of assurance on management's statements referring to any corrective actions taken by the Company after the date of management's assessment.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Provectus Pharmaceuticals, Inc., a development stage company, as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for the period from January 17, 2002 (inception) to December 31, 2010 and for each of the two years in the period ended December 31, 2010 and our report dated March 16, 2011, except as to Note 13 which is as of July 22, 2011 expressed an unqualified opinion thereon.

/S/ BDO USA, LLP

Chicago, Illinois
March 16, 2011, except as to Note 13 which is as of July 22, 2011

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 23, 2011, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 11. EXECUTIVE COMPENSATION.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 23, 2011, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 12. 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 definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 23, 2011, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 23, 2011, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 23, 2011, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

Financial Statements

See Index to Consolidated Financial Statements in "Financial and Supplementary Data."

Financial Statement Schedules

None

Exhibits

Exhibits required by Item 601 of Regulation S-K are incorporated herein by reference and are listed on the attached Exhibit Index, which begins on page X-1 of this Amendment No. 1 to our Annual Report on Form 10-K/A.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

July 22, 2011

PROVECTUS PHARMACEUTICALS, INC.

By: /s/ Peter R. Culpepper
Peter R. Culpepper
Chief Financial Officer and Chief Operating Officer

INDEX TO FINANCIAL STATEMENTS

The following financial statements are included in Part II, Item 8:

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
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, 2010 and 2009 and the related consolidated statements of operations, stockholders' equity, and cash flows for the period from January 17, 2002 (inception) to December 31, 2010 and for each of the two years in the period ended December 31, 2010. 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. 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, 2010 and 2009, and the results of its operations and its cash flows for the period from January 17, 2002 (inception) to December 31, 2010 and for each of the two years in the period ended December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Provectus Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 16, 2011, except as to Note 13 which is as of July 22, 2011 expressed an adverse opinion thereon.

As described in Note 13, the 2010 consolidated financial statements have been restated for a correction of an error to reclassify preferred stock from temporary equity to permanent equity.

/S/ BDO USA, LLP

Chicago, Illinois
March 16, 2011, except as to Note 13 which is as of July 22, 2011

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

CONSOLIDATED BALANCE SHEETS

	December 31, 2010 (As Restated See Note 13)	December 31, 2009
Assets		
Current Assets		
Cash and cash equivalents	$ 8,086,200	$ 3,237,178
Total Current Assets	8,086,200	3,237,178
Equipment and furnishings, less accumulated depreciation of $409,442 and $400,587	21,320	30,175
Patents, net of amortization of $5,447,257 and $4,776,137, respectively	6,268,188	6,939,308
Other assets	27,000	27,000
	$ 14,402,708	$ 10,233,661
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable – trade	$ 418,477	$ 220,251
Accrued compensation and payroll taxes	781,262	149,836
Accrued consulting expense	110,000	42,260
Pension liability	—	345,000
Other accrued expenses	40,000	69,804
Total Current Liabilities	1,349,739	827,151
Long-Term Liability		
Warrant liability	2,353,396	—
Total Liabilities	3,703,135	827,151
Stockholders' Equity		
Preferred stock; par value $.001 per share; 25,000,000 shares authorized; 5,389,998 and no shares issued and outstanding, respectively, liquidation preference (in aggregate $4,122,245)	5,390	—
	91,298	67,410

Common stock; par value $.001 per share; 150,000,000 and 100,000,000 shares authorized, respectively; 91,297,883 and 67,410,226 shares issued and outstanding, respectively		
Paid-in capital	96,952,908	77,137,021
Deficit accumulated during the development stage	(86,350,023)	(67,797,921)
Total Stockholders' Equity	10,699,573	9,406,510
	$ 14,402,708	$ 10,233,661

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31, 2010	Year Ended December 31, 2009	Cumulative Amounts from January 17, 2002 (Inception) Through December 31, 2010
Revenues			
OTC product revenue	$ —	$ —	$ 25,648
Medical device revenue	—	—	14,109
Total revenues	—	—	39,757
Cost of sales	—	—	15,216
Gross profit	—	—	24,541
Operating expenses			
Research and development	8,417,303	4,909,414	29,285,498
General and administrative	11,604,526	6,745,597	45,563,001
Amortization	671,120	671,120	5,447,257
Total operating loss	(20,692,949)	(12,326,131)	(80,271,215)
Gain on sale of fixed assets	—	—	55,075
Loss on extinguishment of debt	—	—	(825,867)
Investment income	1,202	3,817	650,343
Gain on change in fair value of warrant liability	2,139,645	—	2,139,645
Net interest expense	—	—	(8,098,004)
Net loss	$ (18,552,102)	$ (12,322,314)	$ (86,350,023)
Dividends on preferred stock	(10,407,867)	—	
Net loss applicable to common shareholders	$ (28,959,969)	$ (12,322,314)	
Basic and diluted loss per common share	$ (0.37)	$ (0.21)	
Weighted average number of common shares outstanding – basic and diluted	78,817,965	59,796,632	

See accompanying notes to consolidated financial statements.

F-3

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

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred Stock		Common Stock				
	Number of Shares	Par Value	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
Employee compensation from stock options	—	—	—	—	15,612	—	15,612
Issuance of stock pursuant to Regulation S	—	—	2,469,723	2,469	790,668	—	793,137
Issuance of stock and warrants pursuant to	—	—	1,930,164	1,930	1,286,930	—	1,288,861

Regulation D							
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 and warrants 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	—	—	—	—	39,529	—	39,529

to interest expense							
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
Issuance of stock for services	—	—	719,246	719	676,024	—	676,743
Issuance of stock for interest payable	—	—	194,327	195	183,401	—	183,596
Issuance of warrants for services	—	—	—	—	370,023	—	370,023
Exercise of warrants and stock options	—	—	1,245,809	1,246	1,188,570	—	1,189,816
Employee compensation from stock options	—	—	—	—	1,862,456	—	1,862,456
Issuance of stock and warrants pursuant to Regulation D	—	—	10,092,495	10,092	4,120,329	—	4,130,421
Debt conversion to common stock	—	—	2,377,512	2,377	1,573,959	—	1,576,336
Beneficial conversion related to interest expense	—	—	—	—	16,447	—	16,447
Net loss for the year ended 2006	—	—	—	—	—	(8,870,579)	(8,870,579)
Balance, at December 31, 2006	—	$ —	42,452,366	$ 42,452	$ 50,680,353	$ (35,200,405)	$ 15,522,400
Issuance of stock for services	—	—	150,000	150	298,800	—	298,950
Issuance of stock for interest payable	—	—	1,141	1	1,257	—	1,258
Issuance of warrants for services	—	—	—	—	472,635	—	472,635
Exercise of warrants and stock	—	—	3,928,957	3,929	3,981,712	—	3,985,641

options							
Employee compensation from stock options	—	—	—	—	2,340,619	—	2,340,619
Issuance of stock and warrants pursuant to Regulation D	—	—	2,376,817	2,377	1,845,761	—	1,848,138
Debt conversion to common stock	—	—	490,000	490	367,010	—	367,500
Net loss for the year ended 2007	—	—	—	—	—	(10,005,631)	(10,005,631)
Balance, at December 31, 2007	—	$ —	49,399,281	$ 49,399	$ 59,988,147	$ (45,206,036)	$ 14,831,510
Issuance of stock for services	—	—	350,000	350	389,650	—	390,000
Issuance of warrants for services	—	—	—	—	517,820	—	517,820
Exercise of warrants and stock options	—	—	3,267,795	3,268	2,636,443	—	2,639,711
Employee compensation from stock options	—	—	—	—	1,946,066	—	1,946,066
Net loss for the year ended 2008	—	—	—	—	—	(10,269,571)	(10,269,571)
Balance, at December 31, 2008	—	$ —	53,017,076	$ 53,017	$ 65,478,126	$ (55,475,607)	$ 10,055,536
Issuance of stock for services	—	—	796,012	796	694,204	—	695,000
Issuance of warrants for services	—	—	—	—	1,064,210	—	1,064,210
Exercise of warrants and stock options	—	—	3,480,485	3,480	2,520,973	—	2,524,453
Employee compensation from stock options	—	—	—	—	870,937	—	870,937
Issuance of stock and warrants pursuant to Regulation D			10,116,653	10,117	6,508,571	—	6,518,688
	—	—	—	—	—	(12,322,314)	(12,322,314)

Net loss for the year ended 2009							
Balance, at December 31, 2009	—	$ —	67,410,226	$ 67,410	$ 77,137,021	$ (67,797,921)	$ 9,406,510
Issuance of stock for services	—	—	776,250	776	855,837	—	856,613
Issuance of warrants for services	—	—	—	—	1,141,593	—	1,141,593
Exercise of warrants and stock options	—	—	3,491,014	3,491	3,100,189	—	3,103,680
Issuance of common stock pursuant to Regulation S	—	—	559,000	559	418,691	—	419,250
Issuance of common stock and warrants pursuant to Regulation D	—	—	11,168,067	11,169	6,335,820	—	6,346,989
Issuance of preferred stock pursuant to Regulation D	13,283,324	13,283	—	—	4,204,107	—	4,217,390
Preferred stock conversions into common stock	(7,893,326)	(7,893)	7,893,326	7,893	—	—	—
Employee compensation from stock options	—	—	—	—	3,759,650	—	3,759,650
Net loss for the year ended 2010	—	—	—	—	—	(18,552,102)	(18,552,102)
Balance, at December 31, 2010 (As Restated, See Note 13)	5,389,998	$ 5,390	91,297,883	$ 91,298	$ 96,952,908	$ (86,350,023)	$ 10,699,573

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31, 2010	Year Ended December 31, 2009	Cumulative Amounts from January 17, 2002 (Inception) through December 31, 2010
Cash Flows From Operating Activities			
Net loss	$ (18,552,102)	$ (12,322,314)	$ (86,350,023)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	8,855	9,354	432,443
Amortization of patents	671,120	671,120	5,447,257
Amortization of original issue discount	—	—	3,845,721
Amortization of commitment fee	—	—	310,866
Amortization of prepaid consultant expense	—	—	1,295,226
Amortization of deferred loan costs	—	—	2,261,584
Accretion of United States Treasury Bills	—	—	(373,295)
Loss on extinguishment of debt	—	—	825,867
Loss on exercise of warrants	—	—	236,146
Beneficial conversion of convertible interest	—	—	55,976
Convertible interest	—	—	389,950
Compensation through issuance of stock options	3,759,650	870,937	10,845,751
Compensation through issuance of stock	—	—	932,000
Issuance of stock for services	856,613	695,000	8,264,261
Issuance of warrants for services	1,141,593	1,064,210	3,739,427
Issuance of warrants for contractual obligations	—	—	985,010
Gain on sale of equipment	—	—	(55,075)
Gain on change in fair value of warrant liability	(2,139,645)	—	(2,139,645)
(Increase) decrease in assets			
Prepaid expenses and other current assets	—	50,691	—
Increase (decrease) in liabilities			
Accounts payable	198,226	(46,842)	414,832
Accrued expenses	324,362	411,700	1,080,892
Net cash used in operating activities	(13,731,328)	(8,596,144)	(47,554,829)
Cash Flows From Investing Activities			
Proceeds from sale of fixed assets	—	—	180,075
Capital expenditures	—	(5,839)	(67,888)
Proceeds from investments	—	—	37,010,481
Purchases of investments	—	—	(36,637,186)
Net cash (used in) provided by investing activities	—	(5,839)	485,482
Cash Flows From Financing Activities			
Net proceeds from loans from stockholder	—	—	174,000

Proceeds from convertible debt	—	—	6,706,795
Net proceeds from sales of preferred stock and warrants	8,908,131	—	8,908,131
Net proceeds from sales of common stock and warrants	6,766,239	6,518,688	28,264,008
Proceeds from exercises of warrants and stock options	2,905,980	2,524,453	14,454,703
Cash paid to retire convertible debt	—		