PROVECTUS BIOPHARMACEUTICALS, INC.
Form 424B3
April 30, 2014
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PROSPECTUS SUPPLEMENT NO. 4 **Filed pursuant to Rule 424(b)(3)**
(to Prospectus dated April 16, 2013) **Registration No. 333-187803**

PROVECTUS BIOPHARMACEUTICALS, INC.

8,453,941 Shares of Common Stock

This prospectus supplement relates to the prospectus dated April 16, 2013, which permits the resale of the following securities by the selling securityholders identified in the prospectus, as amended and supplemented from time to time:

- 3,400,001 shares of common stock issuable upon conversion of the Series A 8% Convertible Preferred Stock sold in our February 22, 2013 offering;
- 4,250,000 shares of common stock issuable upon exercise of the warrants sold in our February 22, 2013 offering which may be exercised at a price of $1.00 per share; and
- an estimated 803,940 shares of common stock issuable in lieu of the cash payment of dividends on the Series A 8% Convertible Preferred Stock sold in our February 22, 2013 offering payable through February 22, 2016.

We will pay the expenses of registering the shares, but we are not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering. We will, however, receive the exercise price of the warrants if and when the warrants are exercised for cash by the securityholders.

This prospectus supplement is being filed to update, amend, and supplement the information previously included in the prospectus with the information contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2014 (the 10-K). Accordingly, we have attached the 10-K to this prospectus supplement. You should read this prospectus supplement together with the prospectus, which is to be delivered with this prospectus supplement.

Our common stock is quoted on the OTCQB under the symbol PVCT. On April 29, 2014, the last reported sale price of our common stock was $2.35 per share.

Investing in our common stock involves risk. See Risk Factors beginning on page 4 of the prospectus, as amended and supplemented by the Risk Factors beginning on page 19 of the 10-K, to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the prospectus or this prospectus supplement. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is April 30, 2014.

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2013

¨ **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 BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**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). x 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	x
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

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 28, 2013 was $77,150,241 (computed on the basis of $0.65 per share).

The number of shares outstanding of the registrant s common stock, par value $.001 per share, as of March 7, 2014 was 172,450,253.

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, 2013, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on June 16, 2014.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K 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 expressi intended to identify forward-looking statements. While we believe that the expectations reflected in our forward-looking statements are reasonable, we can give no assurance that such expectations will prove correct. Forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from the future results, performance, or achievements expressed in or implied by any forward-looking statement we make. Some of the relevant risks and uncertainties that could cause our actual performance to differ materially from the forward-looking statements contained in this report are discussed below under the heading Risk Factors and elsewhere in this Annual Report on Form 10-K. We caution investors that these discussions of important risks and uncertainties are not exclusive, and our business may be subject to other risks and uncertainties which are not detailed there. Investors are cautioned not to place undue reliance on our forward-looking statements. We make forward-looking statements as of the date on which this Annual Report on Form 10-K 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.

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PART I

ITEM 1. BUSINESS.

General

Provectus Biopharmaceuticals, Inc., a Delaware corporation formed in 2002, together with its six wholly owned subsidiaries and one majority owned subsidiary managed on a consolidated basis, referred to herein as we, us, and our, is a development-stage biopharmaceutical 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 various other non-core technologies. We have transferred all our intellectual property related to OTC products and non-core 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 drug candidates and our progress in developing those candidates for these indications:

PV-10	Prepare for Breakthrough Therapy Designation request 2013 into 2014
Melanoma	Finalized Phase 2 data October 2012 and September 2013
	End-of-Phase 2 FDA meeting April 2010, March 2011, and October 2011
	Phase 2 study completed May 2010
	Phase 2 treatments completed September 2009
	Phase 2 recruitment completed May 2009
	Phase 2 study initiated September 2007
	Orphan drug status January 2007
PH-10	

Psoriasis	Toxicity study research and development for advanced studies 2012, 2013 and into 2014
	Phase 2c randomized study final data collection February 2012
	Phase 2c randomized study initiated December 2010 and completed August 2011
	Phase 2 study completed April 2010
	Phase 2 recruitment completed October 2009
	Replacement Phase 2 initiated July 2009 due to dose regimen change
	Phase 2 study initiated November 2007
PH-10	Toxicity study research and development for advanced studies 2012, 2013 and into 2014
Atopic Dermatitis	
	Phase 2 study completed September 2009
	Phase 2 recruitment completed June 2009
	Phase 2 study initiated June 2008
PV-10	Assessing further development 2013 and 2014 in conjunction with Moffitt Cancer Center research
Breast Cancer	
	Phase 1 study completed July 2008
	Phase 1 initial cohort treatment completed April 2006
	Phase 1 study initiated October 2005
PV-10	Phase 1 protocol expansion September 2012 through 2013 into 2014
Liver Metastasis	Orphan drug status April 2011
	Phase 1 patient accrual and treatment completed January 2011 Phase 1 study initiated October 2009

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PV-10	Moffitt Cancer Center initiates Phase 1 feasibility study to detect immune cell infiltration into melanomas treated by PV-10 in January 2013 into 2014

Mechanism of Action

In addition to clinical trials, patients enrolled in the compassionate use or expanded access 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 injectable form of rose bengal disodium (Rose Bengal), for direct injection into tumors. It is an immuno-chemoablative agent that when injected intralesionally is tantamount to an in situ vaccination following acute and durable necrosis of diseased tissue. 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 recurrent and 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.

Recurrent Melanoma

A Type C meeting was held with the FDA s Division of Oncology Products 2 on December 16, 2013. The purpose of the meeting was to determine which of the available paths that our novel investigational oncology drug PV-10 will take in pursuit of initial FDA approval and commercialization. PV-10, a 10% solution of rose bengal disodium, is designed to selectively target and destroy cancer cells without harming surrounding healthy tissue, while inducing a secondary tumor-specific immune response. As a result of this meeting, we will submit data from its Phase 2 study in a formal breakthrough therapy designation (BTD) request, and should receive a decision within 60 days of receipt of that request.

With the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) in July 2012, the Food and Drug Administration (FDA) was given powerful expedited tools to speed patient access to innovative medicines for serious or life-threatening conditions. FDASIA initiatives such as breakthrough therapy designation are designed to accelerate approval for new drugs that show preliminary clinical evidence of a large treatment effect. A key feature of BTD authorizes the FDA to take steps to ensure that the design of the clinical trials are as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment. Requests for BTD are reviewed and granted or rejected within 60 days of receipt. As we have previously reported, based on rapid tumor destruction in a positive Phase 2 trial in melanoma patients receiving PV-10 (protocol PV-10-MM-02), we sought input from the FDA regarding our current development plan. FDA guidance encourages sponsors to seek such advice prior to formal request for designation.

We believe that this meeting with the FDA is another significant step forward in streamlining the pathway to initial U.S. approval of PV-10 as the first local agent for recurrent locoregionally advanced melanoma. These patients suffer with troublesome, disfiguring disease that can persist for many years before presenting at distant sites. Our meeting with the FDA established the parameters for submission of a BTD request tailored to addressing the pressing needs of these patients.

The meeting and official meeting minutes provided valuable guidance on a number of issues surrounding the approval path of PV-10:

The FDA agreed with us that treatment of cutaneous and subcutaneous tumors in patients with locally advanced cutaneous melanoma (i.e., recurrent, in-transit or satellite melanoma that has not yet spread from the skin to distant sites) could provide clinical benefit to such patients, particularly if the measured objective responses in patients disease correlated to a demonstrated treatment effect on one or more symptoms of their disease (e.g., pain, infection or significant bleeding).

The FDA agreed to work with us to quantify symptom control in this patient population.

In reference to discussions on the potential for breakthrough therapy designation, FDA advised Provectus to provide objective response rates with adequate information to evaluate the symptomatic treatment effects (e.g. pain, infection, bleeding) in patients presenting with locally advanced cutaneous melanoma who received PV-10 to all lesions.

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The Phase 2 study of PV-10 showed:

- Among all 80 intent-to-treat melanoma patients, 26% achieved a complete response and another 25% achieved a partial response (shrinkage by at least 30%) of their injected study tumors (51% objective response rate, confidence interval 40-63%).

- In the subgroup of melanoma patients that received PV-10 injection into all known disease (28 of the 80 ITT patients), 50% achieved a complete response (71% ORR, CI 51-87%).

- In the subgroup of melanoma patients with locally advanced cutaneous melanoma that received PV-10 injection into all known disease or only had 1 or 2 designated bystander tumors untreated (54 of the 80 ITT patients), a complete response was achieved in 232 of 363 injected tumors (64% of lesions) with the vast majority of these tumors requiring only 1 or 2 injections.

These data show that if a tumor is accessible to PV-10 injection, the drug is likely to destroy that tumor. If approved, PV-10 would be the first tissue-sparing local therapy for recurrent melanoma.

We have continued to observe that the FDA may yet recommend and it may be in our best interest to undertake a small, short bridging study in patients where all tumor burden can be injected. This would allow more frequent dosing than was permitted in the Phase 2 study, presumably akin to the dosing schedule currently used to treat nearly 100 patients under our expanded access protocol, and allow symptomatic endpoints to be prospectively correlated with objective response criteria. We have $18 million in cash reserves and would not require additional capital or the resources of a partner to conduct such a study. If such a study is conducted, it also fits with needs for an international study supportive of licensure in Australia, Europe, China and India.

Non-specific local treatments that temporarily reduce tumor burden, such as surgery and radiation, are the most commonly used cancer therapies today. Furthermore, we believe our clinical and immunologic mechanism data show that it may be possible to delay or prevent melanoma metastasis to distant sites. Measurement of tumor shrinkage via objective response criteria has been considered direct clinical benefit in drug approvals for other skin cancers, and we believe a similar case can be made for PV-10 in locally advanced cutaneous melanoma. As advised by the FDA, we will submit data from the 28 patients in our Phase 2 study who had all existing disease treated in a formal BTD request, and should receive a decision within 60 days of receipt of that request.

While the rapid ablative effect immediately evident in patients treated with PV-10 highlights our path to initial approval, the bystander effect continues to be of scientific interest and studies to quantify systemic tumor-specific immune response in cancer patients are ongoing. This emerging understanding of the secondary effect of tumor ablation with PV-10 is an important foundation for future studies to assess the long-term impact of PV-10 on distant metastasis and possible combination strategies for use of PV-10 in the treatment of cancer patients with more advanced disease.

Ongoing immunologic mechanism of action studies at the Moffitt Cancer Center (Moffitt) have been conducted in 2011, 2012, 2013 and thus far in 2014 to characterize the systemic benefit of PV-10. A feasibility study to detect immune cell infiltration into melanomas treated by PV-10 was commenced in January 2013.

Initial data was presented at the 2012 Society of Surgical Oncology Annual Meeting, confirms that PV-10 immuno-chemoablation of melanoma lesions leads to a systemic response and the induction of systemic anti-tumor immunity. We are assessing whether emerging results from these ongoing studies can be used to support accelerated approval in the U.S. Additionally, data on PV-10 was presented by Moffitt in a poster presentation at the American Association for Cancer Research 2013 Annual Meeting in Washington, DC. The PV-10 combination therapy poster, based upon an abstract entitled Combination of PV-10 immuno-chemoablation and systemic anti-CTLA-4 antibody therapy in murine models of melanoma, authored by Eric Wachter, Savannah Blair, Jamie Singer and Craig Dees, was presented as well.

In August, 2013, Moffitt stated that a single injection (PV-10) may revolutionize melanoma treatment. In their initial study, researchers injected a single dose of PV-10 into mice with melanoma. The result was a significant reduction in the skin cancer lesions, as well as a sizable reduction in melanoma tumors that had spread to the lungs. The researchers said the dye solution appeared to produce a robust anti-tumor immune response and may be safer than existing immunological agents.

Moffitt is currently in the middle of their first human clinical trial of PV-10 for advanced melanoma patients. In addition to monitoring the response of injected melanoma tumors, Moffitt is also measuring the boost in the anti-tumor immune cells of patients after injection. The initial study appears in PLOS ONE, an open-access, peer-reviewed online journal.

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On March 6, 2014, it was reported that PV-10 Immune Mechanism Data to Be Presented at the American Association for Cancer Research Annual Meeting by Moffitt Cancer Center via a Poster Presentation. The poster, based upon abstract #630, entitled Induction of anti-melanoma immunity after intralesional ablative therapy, authored by Hao Liu, Krithika Kodumudi, Amy Weber, Amod A. Sarnaik and Shari Pilon-Thomas, will be presented on Sunday, April 6, 2014.

We also report ongoing progress with our Compassionate Use Program for PV-10 for non-visceral cancers. With nearly 100 patients enrolled in six publicized 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 the treatment of recurrent melanoma in the potential short bridging study and upon potential approval.

We are continuing to assess whether we should conduct any additional work by ourselves, or when to partner with a larger company to further co-develop PV-10, as well as potential paths to accelerated and expedited approval in the U.S. and abroad, including in China and India.

Liver Cancer

According to Global Cancer Facts & Figures, 2nd Edition, liver cancer is the fifth leading cause of deaths related to cancer in the world in men and seventh in women. Approximately 750,000 people are newly diagnosed annually with primary liver cancer, also known as Hepatocellular carcinoma (HCC), with China alone accounting for about 55% of the cases diagnosed each year. The world market for liver cancer drugs is projected to exceed $2.0 billion by 2015 and does not include the full impact of the China market potential.

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 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 (iv) 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 with the potential for accelerated approval.

In April 2011, we received orphan drug designation by the FDA for Rose Bengal, the active ingredient in PV-10, for the treatment of HCC, the most common form of primary liver cancer.

In September 2012, we commenced an expansion of the Phase 1 study, which we continued in 2013 and thus far in 2014. Drug-drug metabolic interaction nonclinical studies of PV-10 and sorafenib provided the data to support additional work within the regulatory framework for this important indication. We plan to commence a potentially pivotal study in 2014. This study is potentially pivotal since it would be powered to enable accelerated approval under the auspices of a proposed Breakthrough Therapy Designation request for PV-10 to treat primary liver cancer.

We collaborated with XenoTech, a preclinical CRO and pioneer in collaborative research surrounding in vitro drug metabolism and pharmacokinetics (DMPK) services, in writing an article describing a study to determine the potential of rose bengal disodium to cause drug-drug interactions which has been published by Xenobiotica, a peer-reviewed scientific journal that publishes comprehensive research papers on pharmacokinetics (the study of distribution, metabolism, disposition and excretion of drugs). The published research indicated that the risk of PV-10 causing clinically relevant drug-drug interactions is likely minimal. PV-10, a 10% solution of rose bengal that is currently under clinical investigation as a novel cancer therapeutic, is designed to selectively target and destroy cancer cells without harming surrounding healthy tissue, minimizing the potential for systemic side effects.

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The study was undertaken prior to initiation of the now ongoing testing of PV-10 plus sorafenib (cohort 2) in a clinical trial of PV-10 intralesional injection in hepatocellular carcinoma patients taking a stable dose of sorafenib. Sorafenib is a competitive inhibitor of cytochrome P450 (CYP) drug metabolism enzymes and is reliant on the UDP-glucuronosyltransferase (UGT) pathway for efficient clearance. CYP and UGT enzymes help to biotransform small lipophilic drugs like sorafenib into water-soluble excretable metabolites.

Provectus researchers collaborated with XenoTech s experts to design the appropriate in vitro experiments necessary to assess the risk for potential liability when rose bengal is co-administered with other drugs in humans. Rose bengal, known for inducing singlet oxygen on exposure to light, can cause erroneous results in conventional in vitro test systems. These assay artifacts were shown to be test system dependent in DMPK studies. XenoTech scientists successfully tailored experiments to ascertain CYP and UGT inhibition potential in more appropriate model systems.

Breast Cancer

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 continued to demonstrate this objective in 2011, 2012, 2013, and expect to do so in 2014. We are now in a position for a Phase 2 study in recurrent breast carcinoma with our lead oncology drug product candidate PV-10. We are evaluating potential for further development of PV-10 to treat recurrent breast cancer based on the published data provided by Moffitt as well as interest to address this important indication.

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 additional PV-10 clinical studies. The majority of patients enrolled in the program have been treated for melanoma, with other patients for other indications such as recurrent squamous cell carcinoma and scalp sarcoma.

Additionally, we are considering a clinical study of PV-10 for pancreatic cancer as well as other solid tumor indications.

Dermatology (PH-10)

Our prescription drug candidate PH-10 is an aqueous hydrogel formulation of Rose Bengal for topical administration to the skin. It is a novel nonsteroidal anti-inflammatory agent that interacts with ambient and other light sources. 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 out licensing 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 August 2011, we completed follow-up of all Phase 2c patients and communicated data of the study to both prospective partners as well as the public market in early 2012.

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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 enrolled 99 subjects at four different sites, which began in December 2010. The subjects were randomized sequentially by center to one of four treatment cohorts, and assessed efficacy and safety of topical PH-10 applied once daily to areas of mild to moderate plaque psoriasis. The primary efficacy endpoint was 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 was incidence of adverse experiences, including pain and dermatologic/skin toxicity (incidence, severity, frequency, duration and causality). The secondary outcome measures were (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 was 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 over 90 subjects, this trial is the largest dermatological trial that we have conducted to date.

The results of this study helped define the parameters necessary for the design of a pivotal Phase 3 trial, and it was an important milestone on the regulatory pathway leading towards commercialization. In addition, we ve held discussions

with a number of potential out licensing partners, and we believe this Phase 2c trial has further solidified the commercial viability of PH-10 in these discussions. We have also continued important toxicity study research and development in 2012, 2013 and thus far in 2014 to prepare for a successful Phase 3 study and to support a successful New Drug Approval filing.

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.

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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. We have also continued important toxicity study research and development in 2012, 2013 and thus far in 2014 to prepare for continued development in this important indication and to support a successful New Drug Approval filing.

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

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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. We now intend to license the Pure-ific product, a strategy we have been discussing with interested groups. Additionally, we also intend to sell a majority stake in the underlying assets via a non-core spin-out transaction, as discussed below.

On December 15, 2011, we sold Units to accredited investors which included shares of common stock in Pure-ific and a warrant to purchase 3/4 of a share of the Company s common stock. A total of 666,666 Units were sold for gross proceeds of $500,000 resulting in the sale of a 33% non-controlling interest in Pure-ific. At the time of the sale and as of December 31, 2011, the carrying value of the net assets in Pure-ific was $0. The sale also resulted in the issuance of warrants to purchase 500,000 shares of the Company s common stock at an exercise price of $1.25 per share with a five-year term. We intend to use the proceeds, after deducting offering expenses of approximately $56,500, to spin-off Pure-ific as a new publicly-traded company, a process we have initiated but have not yet completed. Network 1 Financial Securities, Inc., served as placement agent for the offering.

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 of 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 non-core 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 our non-core 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 manufacturers.

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

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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 $3,595,555 for 2013 included payroll of $1,459,057, consulting and contract labor of $1,317,472, lab supplies and pharmaceutical preparations of $310,160, legal of $262,720, insurance of $161,268, rent and utilities of $78,512, and depreciation expense of $6,366. Research and development costs totaling $5,005,459 for 2012 included payroll of $2,536,818, consulting and contract labor of $2,008,270, lab supplies and pharmaceutical preparations of $47,808, legal of $231,430, insurance of $97,728, rent and utilities of $77,238, and depreciation expense of $6,167. Research and development costs totaling $8,807,896 for 2011 included payroll of $6,182,147, consulting and contract labor of $2,238,765, lab supplies and pharmaceutical preparations of $57,467, legal of $161,068, insurance of $92,859, rent and utilities of $68,234, and depreciation expense of $7,356.

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.

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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, non-core technologies 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		February 11, 2003	October 30, 2016

	Methods and apparatus for optical imaging; see discussion under Medical Devices in Description of Business		
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

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U.S. Patent No	Title and Cross Reference	Issue Date	Expiration Date
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
7,863,047	Improved intracorporeal medicaments for photodynamic treatment of disease; see discussion under Dermatology in Description of Business	January 4, 2011	October 30, 2016
8,470,296	Improved intracorporeal medicaments for high energy photodynamic treatment of disease; see discussion under Dermatology in Description of Business	June 25, 2013	June 28, 2022
8,530,675	Process for the synthesis rose bengal and related xanthenes; see discussion under Oncology in Description of Business	September 10, 2013	July 13, 2031
8,557,298	Chemotherapeutic agents for cancer; see discussion under Oncology in Description of Business	October 15, 2013	June 23, 2020

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

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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.

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;

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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

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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 lab technician, a contract research associate, an analytical chemist, and an information technology consultant.

Our executive officers are:

H. Craig Dees, Ph.D., 62, 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 Ingelheim 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., 55, 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., 51, currently serves as our Chief Technology Officer since May 14, 2012 and prior to that served as Executive Vice President Pharmaceuticals and as a member of our board of directors since we acquired PPI on April 23, 2002 until May 14, 2012. 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.

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Peter R. Culpepper, 54, 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.

Equity Financing During 2013

During the three months ended March 31, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $48,750. During the three months ended March 31, 2013, the Company issued 1,924,973 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $409,640. During the three months ended March 31, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $4,045,510. The Company accepted subscriptions, in the aggregate, for 5,394,013 shares of common stock and five year warrants to purchase 7,277,264 shares of common stock. Investors received five year fully vested warrants to purchase up to 100% to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid $522,640 and issued five year fully vested warrants to purchase 539,401 shares of common stock with an exercise price of $1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc.

On February 22, 2013, the Company entered into a Securities Purchase Agreement with certain accredited investors for the issuance and sale in a private placement of an aggregate of $2,550,000 of units, at a purchase price of $0.75 per unit. Each Unit consisted of one share of Series A 8% convertible preferred stock, par value $.001 per share, and a warrant to purchase one and one-quarter shares of the Company s common stock, par value $.001 per share (subject to adjustment) at an exercise price of $1.00 per whole share (subject to adjustment). The Company used the net proceeds of the Private Placement for working capital, FDA trials, securing licensing partnerships, and general corporate purposes. Subject to the terms and conditions of the Purchase Agreement, each of the Investors purchased, and the Company sold and issued, the Units. Each of the parties gave customary representations and warranties, and the Investors made certain representations and warranties concerning their suitability and their status as accredited investors. In accordance with the terms of the Purchase Agreement, the Company entered into a Registration Rights Agreement with each of the Investors (the Registration Rights Agreement). Under the Registration Rights Agreement, the Company is required to prepare and file with the SEC a registration statement on Form S-1 under the Securities Act of 1933 within 45 calendar days of the effective date of the Registration Rights Agreement covering the resale of the shares of Common Stock issued to the Investors (a) upon conversion of the Series A 8% Convertible Preferred Stock and (b) upon exercise of the Warrants. Pursuant to the Registration Rights Agreement, if (i) the Registration Statement is not filed with the SEC on or prior to the Filing Deadline, (ii) the Company fails to file with the SEC a request for acceleration of the Registration Statement within five trading days after the SEC notifies the Company that it will not review the Registration Statement or the Registration Statement will not be subject to further review, (iii) the Company fails to file a pre-effective amendment and otherwise respond in writing to comments made by the

SEC with respect to the Registration Statement within 10 calendar days after receipt of comments or notice from the SEC that such amendment is required in order for the Registration Statement to be declared effective, (iv) the Registration Statement is not declared effective by the SEC on or prior to the 75th day after the effective date of the Registration Rights Agreement (or the 140th day after the effective date of the Registration Rights Agreement if the SEC determines to review the Registration Statement), or (v) the Company fails to continuously maintain the effectiveness of the Registration Statement, the Company will incur liquidated damages to the Investors on the date such failure occurs and on each monthly anniversary of the date such failure occurred until such failure is cured, in cash in an amount that is equal to the product of (A) 2.0% multiplied by (B) each Investor s purchase price. The Registration Rights Agreement also contains mutual indemnifications by the Company and each Investor which the Company believes are customary for transactions of this type. Pursuant to the Purchase Agreement, the Company issued an aggregate of 3,400,001 shares of Series A 8% Convertible Preferred Stock to the Investors. The Series A 8% Convertible Preferred Stock has the rights, privileges, preferences and restrictions set forth in the Certificate of Designation filed with the Secretary of State of the State of Nevada on February 21, 2013. The Certificate

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of Designation authorizes for issuance up to 5,000,000 shares of Series A 8% Convertible Preferred Stock. Under the Certificate of Designation, each share of Series A 8% Convertible Preferred Stock is convertible into one share of Common Stock, subject to adjustment, at the option of the holder at any time, or at the option of the Company, within one trading day after any such time that the volume-weighted average price of Common Stock exceeds $2.25 and the average daily trading volume exceeds 150,000 shares for 30 consecutive trading days. The right of holders of Series A 8% Convertible Preferred Stock to convert the Series A 8% Convertible Preferred Stock is subject to a 4.99% beneficial ownership limitation, which may be increased to 9.99% after providing notice of such increase to the Company. Dividends on the Series A 8% Convertible Preferred Stock will accrue at an annual rate of 8% of the original issue price and will be payable on a quarterly basis. The Company must pay cash dividends on the Series A 8% Convertible Preferred Stock in certain circumstances but may elect to satisfy its obligation to pay quarterly dividends either in cash or by distribution of Common Stock if the Company satisfies certain conditions set forth in the Certificate of Designation. Subject to the beneficial ownership limitations, holders of the Series A 8% Convertible Preferred Stock will be entitled to vote together with the holders of Common Stock, and not as a separate class, on an as-converted basis, except as otherwise required by Nevada law and except for certain corporate actions for which holders of the Series A 8% Convertible Preferred Stock will vote as a separate class. The Certificate of Designation contains customary anti-dilution protection. In addition, for a period of five years after the first issuance of the Series A 8% Convertible Preferred Stock, if the Company issues or is deemed to have issued additional shares of Common Stock without consideration or for a consideration per share less than the applicable conversion price, which is initially $0.75 per share, then the conversion price of the Series A 8% Convertible Preferred Stock will be reduced, concurrently with such issue, to the consideration per share received by the Company for such issue or deemed issue of the additional shares of Common Stock. The Series A 8% Convertible Preferred Stock ranks senior to the Common Stock and on parity with the Company s existing 8% Convertible Preferred Stock with respect to distributions of assets upon liquidation, dissolution or winding up of the Company and the payment of dividends. Pursuant to the Purchase Agreement, the Company issued an aggregate of 4,250,000 Warrants to the Investors. The Warrants contain a cashless exercise provision and are immediately exercisable and will expire on the fifth anniversary of their issuance. The right of holders of Warrants to exercise Warrants for Common Stock will be subject to a 4.99% beneficial ownership limitation, which may be increased to 9.99% after providing notice of such increase to the Company. The Warrants contain customary anti-dilution protection. In addition, for a period of five years after the first issuance of Series A 8% Convertible Preferred Stock, if the Company issues or is deemed to have issued additional rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or convertible securities without consideration or for a consideration per share less than the applicable exercise price, which is initially $1.00 per share, then the exercise price of the Warrants will be reduced, concurrently with such issue, to the consideration per share received by the Company for such issue or deemed issue of the additional rights, options or warrants. The foregoing descriptions of the Purchase Agreement, the Registration Rights Agreement, the Securities, the Certificate of Designation and the transactions contemplated therein are qualified in their entirety by reference to the full text of such agreements and instruments, which are filed as exhibits hereto and are incorporated herein by reference. Such agreements and instruments have been included to provide investors and security holders with information regarding their terms. They are not intended to provide any other factual information about the Company. The transaction documents contain certain representations, warranties and indemnifications resulting from any breach of such representations or warranties. Investors and security holders should not rely on the representations and warranties as characterizations of the actual state of facts because they were made only as of the respective dates of such documents. In addition, information concerning the subject matter of the representations and warranties may change after the respective dates of such documents, and such subsequent information may not be fully reflected in the Company s public disclosures. In January 2014, the remaining Series A 8% Convertible Preferred Stock was converted to shares of common stock, and there are currently no shares of Series A 8% Convertible Preferred Stock outstanding.

During the three months ended June 30, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $49,500. During the three months ended June 30,

2013, the Company issued 2,605,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $931,655. During the three months ended June 30, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $2,641,501. The Company accepted subscriptions, in the aggregate, for 3,522,001 shares of common stock and five year warrants to purchase 5,283,003 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid $314,173, accrued $32,500 at June 30, 2013 which was paid in July 2013 and issued five year fully vested warrants to purchase 352,200 shares of common stock with an exercise price of $1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc.

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During the three months ended September 30, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $51,250. During the three months ended September 30, 2013, the Company issued 442,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $186,223. During the three months ended September 30, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $4,613,037. The Company accepted subscriptions, in the aggregate, for 6,150,718 shares of common stock and five year warrants to purchase 9,226,077 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid $564,686 and issued five year fully vested warrants to purchase 615,072 shares of common stock with an exercise price of $1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc. During the three months ended September 30, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $2,687,500. The Company accepted subscriptions, in the aggregate, for 3,583,333 shares of common stock and five year warrants to purchase 5,375,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company used the proceeds for working capital and other general corporate purposes. Maxim Group LLC served as placement agent for the offering. In connection with the offering, the Company paid $349,375 and issued five year fully vested warrants to purchase 358,333 shares of common stock with an exercise price of $1.00 to Maxim Group LLC, which represents 10% of the total number of shares of common stock sold to investors solicited by Maxim Group LLC.

During the three months ended December 31, 2013, the Company issued 275,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $214,000. During the three months ended December 31, 2013, the Company issued 209,473 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $259,306. During the three months ended December 31, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $5,820,588. The Company accepted subscriptions, in the aggregate, for 7,760,784 shares of common stock and five year warrants to purchase 11,641,176 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid $747,302 and issued five year fully vested warrants to purchase 776,078 shares of common stock with an exercise price of $1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc. During the three months ended December 31, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $1,312,500. The Company accepted subscriptions, in the aggregate, for 1,750,000 shares of common stock and five year warrants to purchase 2,625,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company used the proceeds for working capital and other general corporate purposes. Maxim Group LLC served as placement agent for the offering. In connection with the offering, the Company paid $170,625 and issued five year fully vested warrants to purchase 175,000 shares of common stock with an exercise price of $1.00 to Maxim Group LLC, which represents 10% of the total number of shares of common stock sold to

investors solicited by Maxim Group LLC.

The issuances of the securities were exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 4(2) and Rule 506 promulgated under Regulation D thereunder as transactions not involving a public offering.

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. Reference to our website does not constitute incorporation by reference of the information contained on the site and should not be considered part of this document.

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All filings made by us with the SEC may be copied or read at the SEC s Public Reference Room at 100 F Street NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC as we do. The website is http://www.sec.gov.

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, 2013, we have incurred net losses of $146 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 non-core 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 other non-core technologies;
- further develop our non-core 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 non-core

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 2015 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 2015. However, we may need additional capital in 2015 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 expanding Phase 2 atopic dermatitis and psoriasis results, which were significantly developed in 2012 and 2013. 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 other non-core technologies. Although we believe that there is a reasonable basis for our expectation that we will become profitable due to the licensure of PH-10, PV-10 and the sale or licensure of our OTC products and non-core 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 you 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, if necessary, to acquire additional funding through public or private equity or debt financings or other financing sources that may be available; however, our primary interest is to not enter into additional private placements. Nevertheless, 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

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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 intermediary 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 other product candidates that we are developing to be commercially available without a partner. 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 other 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.

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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 additional 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 non-core 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 non-core 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 further developed. 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.

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We cannot be sure that our OTC products or non-core technologies will be licensed or sold in the marketplace.

In order for our OTC products to become commercially successful and our non-core 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 other product 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.

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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 Chief Technology Officer; and

Peter R. Culpepper, CPA, MBA, 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 other product 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 other product 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.

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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 $0.43 per share and as high as $2.59 per share during the period beginning on January 1, 2012 and ending on December 31, 2013. 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;
- speculation inherent in the biotech small-cap industry;
- a relatively thin trading market for our common stock, aside from December 2013 and thus far in 2014, 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; 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.

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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.

None.

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 $5,000 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.

Except as described below, 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.

On January 2, 2013, Glenn Kleba (the Plaintiff) derivatively on behalf of the Company, filed a shareholder derivative complaint in the Circuit Court for the State of Tennessee, Knox County (the Court), against H. Craig Dees, Timothy C. Scott, Eric A. Wachter, and Peter R. Culpepper (collectively, the Executives), Stuart Fuchs, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, together with the Executives, the Individual Defendants), and against the Company as a nominal defendant (the Shareholder Derivative Lawsuit). The Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties, (ii) waste of corporate assets, and (iii) unjust enrichment, all three claims based on the Plaintiff s allegations that the defendants authorized and/or accepted stock option awards in violation of the terms of the Company s 2002 Stock Plan (the Plan) by issuing stock options in excess of the amounts authorized under the Plan and delegated to defendant H. Craig Dees the sole authority to grant himself and the other Executives cash bonuses that the Plaintiff alleges to be excessive.

In April 2013, the Company s Board of Directors established a special litigation committee to investigate the allegations of the Shareholder Derivative Complaint and make a determination as to how the matter should be resolved. The special litigation committee conducted its investigation, and proceedings in the case were stayed pending the conclusion of the committee s investigation. The Company has established a reserve of $100,000 for potential liabilities because such is the amount of the self-insured retention of its insurance policy.

On March 6, 2014, the Company filed a Joint Notice of Settlement (the Settlement) in the Shareholder Derivative Lawsuit. In addition to the Company, the parties to the Settlement are the Plaintiff and the Individual Defendants. By entering into the Settlement, the settling parties have resolved the derivative claims to their mutual satisfaction. The Individual Defendants have not admitted the validity of any claims or allegations and the Plaintiff has not admitted that any claims or allegations lack merit or foundation. By the terms of the Settlement, (i) the Executives each agreed

(A) to re-pay to the Company $2.24 Million of the cash bonuses they received in 2010 and 2011, which amount equals 70% of such bonuses or an estimate of the after-tax net proceeds to each Executive; provided, however, that subject to certain terms and conditions set forth in the term sheet, which sets forth the terms and conditions of the Settlement (the Term Sheet), the Executives are entitled to a 2:1 credit such that total actual repayment may be $1.12 Million each; (B) to reimburse the Company for 25% of the actual costs incurred by the Company as a result of the Shareholder Derivative Lawsuit; and (C) to grant to the Company a first priority security interest in 1,000,000 shares of the Company s common stock owned by each such Executive to serve as collateral for the amounts due to the Company under the Term Sheet; (ii) Drs. Dees and Scott and Mr. Culpepper agreed to retain incentive stock options for 100,000 shares but shall forfeit 50% of the nonqualified stock options granted to each such Executive in both 2010 and 2011. The Term Sheet also requires that each of the Executives enter into new employment agreements with the Company and that the Company adhere to certain corporate governance principles and processes in the future. Under the Settlement, Messrs. Fuchs and Smith and Dr. McMasters have the option to either (A) pay the Company $25,000 cash or (B) forfeit options to purchase 50,000 shares of the Company s common stock. The Company, the Plaintiff and the Individual Defendants will release each other from any and all claims related to the Shareholder Derivative Lawsuit, as well as dismiss the Shareholder Derivative Lawsuit with prejudice upon the Company and the Individual Defendants entering into a formal settlement agreement.

The Settlement remains subject to approval by the Court after notice to the Company s shareholders and a settlement hearing. The hearing on the terms of the proposed settlement will be held to determine whether: (1) the terms and conditions of the

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settlement provided for in the Settlement are fair, reasonable and adequate and in the best interest of the Company and its shareholders, (2) the judgment, as provided for in the Settlement, should be entered, and (3) the request of Plaintiff s counsel for an award of attorneys fees and reimbursement of expenses should be granted.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information and Holders

During 2012, quotations for our common stock were reported on the OTC Bulletin Board under the symbol PVCT. In January 2013, our common stock ceased to be traded on the OTC Bulletin Board and is now trading on the OTC QB Marketplace operated by OTC Markets Group. Our trading symbol remains 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, 2012:

	High	Low
2013		
First Quarter (January 1 to March 31)	$ 0.88	$ 0.55
Second Quarter (April 1 to June 30)	$ 0.80	$ 0.58
Third Quarter (July 1 to September 30)	$ 1.14	$ 0.58
Fourth Quarter (October 1 to December 31)	$ 2.59	$ 0.75
2012		
First Quarter (January 1 to March 31)	$ 0.98	$ 0.83
Second Quarter (April 1 to June 30)	$ 0.93	$ 0.80
Third Quarter (July 1 to September 30)	$ 0.85	$ 0.63
Fourth Quarter (October 1 to December 31)	$ 0.67	$ 0.52

The closing price for our common stock on March 7, 2014 was $1.91. High and low sale price information was obtained from data provided by Yahoo! Inc.

As of March 7, 2014, we had 2,809 shareholders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common 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 on our common stock will be at the discretion of our board of directors.

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Stock Performance Graph

The following graph shows the changes, over the past five-year period, in the value of $100 invested in Provectus common stock, the NASDAQ Composite Total Return Index and a Peer group of companies composed of development stage, biopharmaceutical companies that have a focus on developing oncology compounds. The graph assumes that all dividends are reinvested. We changed the companies comprising the peer group index this year from the peer group of companies used in our performance graph in our Annual Report on Form 10-K for the year ended December 31, 2012 (the 2012 10-K) to correspond with the peer group of companies identified by our compensation consultant in connection with our compensation committee s review of executive and director compensation during the year ended December 31, 2013. The graph below includes results for both the peer group used in the performance graph included in the 2012 10-K, as well as the new peer group.

	2008	2009	2010	2011	2012	2013
Provectus Biopharmaceuticals, Inc.	$ 100.00	$ 98.91	$ 102.17	$ 88.04	$ 60.87	$ 261.96
NASDAQ Composite-Total Returns	$ 100.00	$ 145.34	$ 171.70	$ 170.34	$ 200.57	$ 281.14
New Peer Group	$ 100.00	$ 131.01	$ 128.95	$ 119.37	$ 136.92	$ 118.17
Old Peer Group	$ 100.00	$ 136.96	$ 154.39	$ 150.83	$ 185.41	$ 151.54

Recent Sales of Unregistered Securities

During the three months ended March 31, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $48,750. During the three months ended March 31, 2013, the Company issued 1,924,973 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $409,640. During the three months ended March 31, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $4,045,510. The Company accepted subscriptions, in the aggregate, for 5,394,013 shares of common stock and five year warrants to purchase 7,277,264 shares of common stock. Investors received five year fully vested warrants to purchase up to 100% to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid $522,640 and issued five year fully vested warrants to purchase 539,401 shares of common stock with an exercise price of $1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc.

During the three months ended June 30, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $49,500. During the three months ended June 30, 2013, the Company issued 2,605,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $931,655. During the three months ended June 30, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $2,641,501. The Company accepted subscriptions, in the aggregate, for 3,522,001 shares of common stock and five year warrants to purchase 5,283,003 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of

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common stock together with the warrants was $0.75. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid $314,173, accrued $32,500 at June 30, 2013 which was paid in July 2013 and issued five year fully vested warrants to purchase 352,200 shares of common stock with an exercise price of $1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc.

During the three months ended September 30, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $51,250. On July 22, 2013 the Company entered into a Purchase Agreement with Alpha Capital Anstalt. In consideration of entering into the Purchase Agreement and making the commitment to purchase the Purchase Shares, the Company issued 250,000 shares of the Company s common stock to Alpha Capital Anstalt. Consulting costs charged to operations were $162,500. During the three months ended September 30, 2013, the Company issued 442,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $186,223. During the three months ended September 30, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $4,613,037. The Company accepted subscriptions, in the aggregate, for 6,150,718 shares of common stock and five year warrants to purchase 9,226,077 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid $564,686 and issued five year fully vested warrants to purchase 615,072 shares of common stock with an exercise price of $1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc. During the three months ended September 30, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $2,687,500. The Company accepted subscriptions, in the aggregate, for 3,583,333 shares of common stock and five year warrants to purchase 5,375,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company used the proceeds for working capital and other general corporate purposes. Maxim Group LLC served as placement agent for the offering. In connection with the offering, the Company paid $349,375 and issued five year fully vested warrants to purchase 358,333 shares of common stock with an exercise price of $1.00 to Maxim Group LLC, which represents 10% of the total number of shares of common stock sold to investors solicited by Maxim Group LLC.

During the three months ended December 31, 2013, the Company issued 275,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $214,000. During the three months ended December 31, 2013, the Company issued 209,473 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $259,306. During the three months ended December 31, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $5,820,588. The Company accepted subscriptions, in the aggregate, for 7,760,784 shares of common stock and five year warrants to purchase 11,641,176 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid $747,302 and issued five year fully vested warrants to purchase 776,078 shares of common stock with an exercise price of $1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of

common stock sold to investors solicited by Network 1 Financial Securities, Inc. During the three months ended December 31, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of $1,312,500. The Company accepted subscriptions, in the aggregate, for 1,750,000 shares of common stock and five year warrants to purchase 2,625,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.00 per share. The purchase price for each share of common stock together with the warrants was $0.75. The Company used the proceeds for working capital and other general corporate purposes. Maxim Group LLC served as placement agent for the offering. In connection with the offering, the Company paid $170,625 and issued five year fully vested warrants to purchase 175,000 shares of common stock with an exercise price of $1.00 to Maxim Group LLC, which represents 10% of the total number of shares of common stock sold to investors solicited by Maxim Group LLC.

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The issuances of the securities were exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 4(2) and Rule 506 promulgated under Regulation D thereunder as transactions not involving a public offering.

The Company has used and intends to use the net proceeds of these issuances for working capital, FDA trials, securing licensing partnerships, and general corporate purposes.

For the issuance of securities to executives, see table labeled Equity Compensation Plan Information to be contained in the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 16, 2014, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act, incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

ITEM 6. SELECTED FINANCIAL DATA.

The following table sets forth our selected consolidated financial data and has been derived from our audited consolidated financial statements. Consolidated balance sheets as of December 31, 2013 and 2012, as well as consolidated statements of operations for the years ended December 31, 2013, 2012, and 2011, and the report thereon are included elsewhere in this Annual Report on Form 10-K. The information below should be read in conjunction with our audited consolidated financial statements (and notes thereon) and Management s Discussion and Analysis of Financial Condition and Results of Operations, included below in Item 7.

	Years ended December 31,				
	2013	2012	2011	2010	2009
	(all amounts in thousands except per share data)				
Consolidated Statement of Operations Data:					
Revenues					
OTC product revenue	$	$	$	$	$
Medical device revenue					
Total revenues					
Operating expenses					
Research and development	3,596	5,006	8,808	8,417	4,909
General and administrative	8,761	8,661	11,962	11,605	6,746
Amortization	671	671	671	671	671
Total operating loss	(13,028)	(14,338)	(21,441)	(20,693)	(12,326)
Other income, net	(14,670)	1,769	2,006	2,141	4
Net loss	(27,698)	(12,569)	(19,435)	(18,552)	(12,322)
Dividends on preferred stock	(1,188)	(183)	(247)	(10,408)	
Net loss applicable to common stockholders	$ (28,886)	$ (12,752)	$ (19,682)	$ (28,960)	$ (12,322)
Basic and diluted loss per common share	$ (0.22)	$ (0.11)	$ (0.19)	$ (0.37)	$ (0.21)

Weighted average number of common shares outstanding basic and diluted	132,001	112,987	105,725	78,818	59,797

	As of December 31,				
	2013	**2012**	**2011**	**2010**	**2009**
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 15,696	$ 1,222	$ 7,705	$ 8,087	$ 3,238
Patents, net	4,255	4,926	5,598	6,268	6,939
Other assets	57	56	47	48	57
Total assets	20,008	6,204	13,350	14,403	10,234
Current liabilities	513	511	263	1,350	827
Warrant liability	12,866	1,300	3,067	2,353	
Preferred stock		2	4	5	
Common stock	160	118	110	91	67
Additional paid-in capital	152,520	122,626	115,690	96,953	77,137
Accumulated deficit	(146,051)	(118,353)	(105,784)	(86,350)	(67,797)
Total stockholders equity	6,629	4,393	10,020	10,699	9,407

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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 Annual Report on Form 10-K. 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 3-8 years. Annual amortization of the patents is expected to approximate $671,000 for each of the next three years and $659,000 in 2017 and 2018.

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. 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 uses the Monte-Carlo Simulation model to estimate the fair value of the warrants. Significant assumptions used at December 31, 2013 include a weighted average term of 1.2 years, a 5% probability that the warrant exercise price would be reset, a volatility range between 66.5% and 69.5% and a risk free interest rate range between 0.13% and 0.38%. Significant assumptions used at December 31, 2012 include a weighted average term of 2.2 years, a 5% probability that the warrant exercise price would be reset, a volatility range between 58.9% and 63.4% and a risk free interest rate range between 0.25% and 0.36%.

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Additionally, the Series A and Series C Warrants issued in conjunction with the January 2011 registered direct public offering include a reset provision if the Company issues additional warrants, in certain circumstances as defined in the agreement, below the exercise price of $1.12. At December 31, 2013, the warrant exercise price was reset to $0.675. Significant assumptions used at December 31, 2013 include a weighted average term of 2.0 years, a 5% probability that the warrant exercise price would be further reset, volatility of 64.7% and a risk free interest rate range between 0.38% and 0.78%. Significant assumptions used at December 31, 2012 include a weighted average term of 3.0 years, a 5% probability that the warrant exercise price would be further reset, a volatility range between 58.9% and 63.4% and a risk free interest rate range between 0.25% and 0.36%.

On February 22, 2013, the Company entered into a Securities Purchase Agreement with certain accredited investors for the issuance and sale in a private placement of an aggregate of $2,550,000 of Units at a purchase price of $0.75 per Unit. Each Unit consists of one share of Series A 8% Convertible Preferred Stock, par value $.001 per share, and a warrant to purchase one and one-quarter shares of the Company s common stock, par value $.001 per share (subject to adjustment) at an exercise price of $1.00 per whole share (subject to adjustment). The total Series A 8% Convertible Preferred Stock issued was 3,400,001 shares, and the total warrants were 4,250,000. The Company used the net proceeds of the private placement for working capital, FDA trials, securing licensing partnerships, and general corporate purposes.

The Company determined that warrants issued in February, 2013 with the Series A 8% Convertible Preferred Stock should be classified as liabilities in accordance with ASC 815 because the warrants in question contain exercise price reset features that require the exercise price of the warrants be adjusted if the Company issues certain other equity related instruments at a lower price per share. The preferred stock was determined to have characteristics more akin to equity than debt. As a result, the conversion option was determined to be clearly and closely related to the preferred stock and therefore does not need to be bifurcated and classified as a liability. Significant assumptions used at December 31, 2013 include a weighted average term of 4.1 years, a 5% probability that the warrant exercise price would be reset, volatility of 67.2% and a risk free interest rate range between 0.78% and 1.78%.

Fair Value of Financial Instruments

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, and accounts payable approximate their fair value because of the short-term nature of these items. Cash equivalents are measured on a recurring basis within the fair value hierarchy using Level 1 inputs.

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 2013 and thus far from warrant exercises in 2014. Given our current rate of expenditures and our ability to curtail or defer certain controllable expenditures, we do not need to raise additional capital to further develop PV-10 on our own to treat recurrent melanoma, HCC, recurrent breast cancer, pancreatic cancer and other indications because we plan to license PH-10 for psoriasis and other related indications described as inflammatory dermatoses, strategically monetize PV-10

through appropriate regional license transactions, and also complete the spin-out of Pure-ific Corporation and the other non-core subsidiaries. Additionally, our existing funds are sufficient to meet minimal necessary expenses until well into 2015.

We believe our continued development of PV-10 with existing funds will yield proof-of-concept evidence to support expected best-in-class clinical benefit to treat a wide range of solid tumor recurrences due to its unique immuno-chemoablation mechanism of action. Likewise, we believe our development of PH-10 with existing funds will yield proof-of-concept evidence to support expected best-in-class clinical benefit to treat a wide range of inflammatory dermatoses due to its unique non-steroidal anti-inflammatory mechanism of action.

Our cash and cash equivalents were $15,696,243 at December 31, 2013, compared with $1,221,701 at December 31, 2012. The increase of approximately $14.5 million was due primarily to a substantial increase in the sales of common stock and warrants as well as substantial exercises of warrants coupled with approximately $1.4 million less cash that was used in operating activities in 2013 versus 2012. Additionally thus far in 2014, the Company received approximately $2.7 million in cash due to additional warrant exercises and $539,000 in cash due to stock option exercises.

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By managing variable cash expenses due to minimal fixed costs, we believe our cash and cash equivalents on hand at December 31, 2013, together with approximately $3.2 million received thus far in 2014 due to exercises of warrants and stock options, will be sufficient to meet our current and planned operating needs until well into 2015 without consideration being given to additional cash inflows that might occur from the exercise of existing warrants or future sales of equity securities, although we may, in our sole discretion, direct Alpha Capital Anstalt (Investor) to purchase up to $30,000,000 of our common stock per an existing agreement with Investor.

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 primarily the geographic licensure of PV-10 on the basis of our Phase 2 recurrent melanoma and Phase 1 liver results in certain areas of the world, as well as pursuing a strategic investment strategy, including equity sales to potential pharmaceutical and/or biotech partners. In addition, the data now available and forthcoming from Moffitt Cancer Center in Tampa, Florida has been and is expected to be particularly helpful in supporting our development plans with both the FDA and prospective partners. The geographic areas of interest for PV-10 principally include China, India, Japan and Middle East and North Africa (MENA). We are encouraged by the interest in both PV-10 and PH-10 on a geographic basis and are continuing discussions with potential partners.

We are also considering the global licensure of PV-10 as well since it has come to our attention that this is of interest to potential partners. We have provided data on a confidential basis to both potential global and geographic partners for both PV-10 and PH-10 via a secure electronic data room that is monitored 24 hours a day, seven days a week and houses formal data submissions to the FDA as well as various corporate governance related documents.

We also expect to continue with the majority stake asset sale and licensure of our non-core assets. However, the primary objective of the Company is to strategically monetize the core value of PV-10 and PH-10 through various transactions, leveraging value creation up to and including an appropriate merger and acquisition transaction that includes upfront cash and acquirer stock in exchange for Company ownership as well as a contingency value right (CVR) to facilitate potential upside post-acquisition. We believe regulatory clarity, including one or more breakthrough therapy designations, is determined by specifying the expected approval pathways of both PV-10 and PH-10. This may include the potential for breakthrough therapy designation for PV-10 to treat locally advanced recurrent melanoma and an accelerated approval path for PV-10 to treat this indication. Such clarity will help facilitate transactions with potential partners. Additionally, the existing and forthcoming mechanism of action related clinical and nonclinical data for both PV-10 and PH-10 will further aid in both regulatory clarity and transactions with potential partners.

However, we cannot assure you that we will be successful in either licensing of PH-10 or PV-10, any equity transaction, 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 2014 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. 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.

Plan of Operation

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.

Our current plans include continuing to operate with our four employees during the immediate future, as well as four primary consultants and various vendor relationships, and anticipate adding additional personnel or contract research organizations if necessary 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.

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, and important immunologic data has been corroborated and characterized by institutions such as Moffitt Cancer Center in Tampa, Florida and another leading research facility. We continue to develop clinical trials for these products to show their safety and efficacy, which we believe will continue to be shown based on data in previous studies, and which will result in one or more

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license transactions with pharmaceutical and or biotech partners. Together with our 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 beyond.

Comparison of the Years Ended December 31, 2013 and 2012

Revenues

We had no revenue during the years ended 2013 and 2012.

Research and development

Research and development costs totaling $3,595,555 for 2013 included payroll of $1,459,057, consulting and contract labor of $1,317,472, lab supplies and pharmaceutical preparations of $310,160, legal of $262,720, insurance of $161,268, rent and utilities of $78,512, and depreciation expense of $6,366. Research and development costs totaling $5,005,459 for 2012 included payroll of $2,536,818, consulting and contract labor of $2,008,270, lab supplies and pharmaceutical preparations of $47,808, legal of $231,430, insurance of $97,728, rent and utilities of $77,238, and depreciation expense of $6,167.

The decrease in payroll in 2013 over 2012 is primarily the result of the termination of bonuses and reduced stock-based compensation expense from stock options. The reduction in payroll represents most of the decrease in research and development expenses in 2013 versus 2012. Additionally, consulting and contract labor decreased in 2013 over 2012 due to reduction in warrants for services in 2013 versus 2012.

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

Projects	Actual Cost for 2013	Actual Cost for 2012	Total Costs Incurred To Date
Melanoma	$ -0-	$ -0-	$ 3,018,000
Breast/Other	$ -0-	$ -0-	$ 675,000
Liver	$ -0-	$ -0-	$ 616,000
Psoriasis/Atopic Dermatitis	$ -0-	$ -0-	$ 1,678,000
Payroll	$ 1,459,000	$ 2,537,000	
Indirect costs	$ 2,137,000	$ 2,469,000	
Totals	$ 3,596,000	$ 5,006,000	

General and administrative

General and administrative expenses increased by $100,224 for 2013 to $8,761,264 from $8,661,040 in 2012. The increase is primarily due to an increase in investor relations expense offset by the termination of bonuses and reduced stock-based compensation expense from stock options.

Investment income

Investment income is immaterial for all periods presented.

Change in fair value of warrant liability

Change in fair value of warrant liability increased by $16,439,048 to a loss of $14,671,130 in 2013 from a gain of $1,767,918 in 2012. This activity results from accounting for the warrant liability described in Footnotes 4(f), 4(i), 4(j) and 10 to the financial statements.

Cash Flow

Our cash and cash equivalents were $15,696,243 at December 31, 2013, compared with $1,221,701 at December 31, 2012. The increase of approximately $14.5 million was due primarily to a substantial increase in the sales of common and preferred stock and warrants as well as substantial exercises of warrants coupled with approximately $1.4 million less cash that was used in operating activities in 2013 versus 2012. At our current cash expenditure rate, our cash and cash equivalents will be sufficient to meet our current and planned needs until well into 2015 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 well into 2015 with the cash on hand at December 31, 2013 and with the additional cash inflows thus far in 2014, including $2,672,363 received due to warrant exercises and $538,586 received due to stock option exercises.

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Comparison of the Years Ended December 31, 2012 and 2011

Revenues

We had no revenue during the years ended 2012 and 2011.

Research and development

Research and development costs totaling $5,005,459 for 2012 included payroll of $2,536,818, consulting and contract labor of $2,008,270, lab supplies and pharmaceutical preparations of $47,808, legal of $231,430, insurance of $97,728, rent and utilities of $77,238, and depreciation expense of $6,167. Research and development costs totaling $8,807,896 for 2011 included payroll of $6,182,147, consulting and contract labor of $2,238,765, lab supplies and pharmaceutical preparations of $57,467, legal of $161,068, insurance of $92,859, rent and utilities of $68,234, and depreciation expense of $7,356.

The decrease in payroll in 2012 over 2011 is primarily the result of the termination of bonuses and no employee stock-based compensation expense from stock options. The reduction in payroll represents virtually all of the decrease in research and development expenses in 2012 versus 2011.

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

Projects	Actual Cost for 2012	Actual Cost for 2011	Total Costs Incurred To Date
Melanoma	$ -0-	$ -0-	$ 3,018,000
Breast/Other	$ -0-	$ -0-	$ 675,000
Liver	$ -0-	$ -0-	$ 616,000
Psoriasis/Atopic Dermatitis	$ -0-	$ -0-	$ 1,678,000
Payroll	$ 2,537,000	$ 6,182,000	
Indirect costs	$ 2,469,000	$ 2,626,000	
Totals	$ 5,006,000	$ 8,808,000	

General and administrative

General and administrative expenses decreased by $3,300,808 for 2012 to $8,661,040 from $11,961,848 in 2011. The decrease is primarily due to the result of the termination of bonuses and no employee stock-based compensation expense from stock options.

Investment income

Investment income is immaterial for all periods presented.

Gain on change in fair value of warrant liability

Gain on change in fair value of warrant liability decreased by $236,720 in 2012 to $1,767,918 from $2,004,638 in 2011. This activity results from accounting for the warrant liability described in Footnotes 4(f), 4(i) and 10 to the

financial statements.

Cash Flow

Our cash and cash equivalents were $1,221,701 at December 31, 2012, compared with $7,705,773 at December 31, 2011.

Capital Resources

As noted above, our present cash and cash equivalents are 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 2015 and beyond may come from a partnership agreement or 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 if necessary, 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.

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Recent Accounting Pronouncements

None.

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

We had no holdings of financial or commodity instruments as of December 31, 2013, other than cash and cash equivalents, short-term deposits, money market funds and interest bearing investments in U.S. governmental debt securities. We have accounted for certain warrants issued in March and April 2010, January 2011 and February 2013 as liabilities at their fair value upon issuance, which are remeasured at each period end with the change in fair value recorded in the statement of operations. See note 4 of the consolidated financial statements contained in this Annual Report on Form 10-K.

All of our business is transacted in U.S. dollars and, accordingly, foreign exchange rate fluctuations have not had a significant impact on us, and they are not expected to have a significant impact on us in the foreseeable future.

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 effective as of December 31, 2013, 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. Management conducted an assessment of our internal control over financial reporting as of December 31, 2013 using the framework specified in *Internal*

Control Integrated Framework (1992), published by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, the Chief Executive Officer and Chief Financial Officer concluded that our internal control over financial reporting at December 31, 2013 was effective.

Our independent registered public accounting firm, BDO USA, LLP, assessed the effectiveness of the Company s internal control over financial reporting. BDO USA, LLP has issued an attestation report on our internal control over financial reporting as of December 31, 2013, which is set forth below.

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 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Provectus Biopharmaceuticals, Inc.

Knoxville, Tennessee

We have audited Provectus Biopharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Provectus Biopharmaceuticals, 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.

In our opinion, Provectus Biopharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Provectus Biopharmaceuticals, Inc., a development stage company, as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders equity, and cash flows for the period from January 17, 2002 (inception) to December 31, 2013 and for each of the three years in the period ended December 31, 2013 and our report dated March 13, 2014 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Chicago, Illinois

March 13, 2014

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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 16, 2014, 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 16, 2014, 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 16, 2014, 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 16, 2014, 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 16, 2014, 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 our Annual Report on Form 10-K.

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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.

March 13, 2014

PROVECTUS BIOPHARMACEUTICALS, INC.

By: /s/ H. Craig Dees
H. Craig Dees, Ph.D.
Chief Executive Officer and Chairman of the Board

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacity and on the dates indicated.

Signature	Title	Date
/s/ H. Craig Dees H. Craig Dees, Ph.D.	Chief Executive Officer (principal executive officer) and Chairman of the Board	March 13, 2014
/s/ Peter R. Culpepper Peter R. Culpepper	Chief Financial Officer (principal financial officer), Chief Operating Officer and Chief Accounting Officer	March 13, 2014
/s/ Timothy C. Scott Timothy C. Scott	President and Director	March 13, 2014
/s/ Jan Koe Jan Koe	Director	March 13, 2014
/s/ Kelly M. McMasters Kelly M. McMasters, M.D., Ph.D.	Director	March 13, 2014
/s/ Alfred E. Smith, IV Alfred E. Smith, IV	Director	March 13, 2014

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INDEX TO FINANCIAL STATEMENTS

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

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Provectus Biopharmaceuticals, Inc.

Knoxville, Tennessee

We have audited the accompanying consolidated balance sheets of Provectus Biopharmaceuticals, Inc., a development stage company, as of December 31, 2013 and 2012 and the related consolidated statements of operations, stockholders equity, and cash flows for the period from January 17, 2002 (inception) to December 31, 2013 and for each of the three years in the period ended December 31, 2013. 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 presentation of the financial statements. 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 Biopharmaceuticals, Inc. at December 31, 2013 and 2012, and the results of its operations and its cash flows for the period from January 17, 2002 (inception) to December 31, 2013 and for each of the three years in the period ended December 31, 2013, 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 Biopharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 13, 2014 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Chicago, Illinois

March 13, 2014

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PROVECTUS BIOPHARMACEUTICALS, INC.

(A Development-Stage Company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2013	December 31, 2012
Assets		
Current Assets		
Cash and cash equivalents	$ 15,696,243	$ 1,221,701
Equipment and furnishings, less accumulated depreciation of $429,331 and $422,965, respectively	30,113	29,829
Patents, net of amortization of $7,460,617 and $6,789,497, respectively	4,254,828	4,925,948
Other assets	27,000	27,000
	$ 20,008,184	$ 6,204,478

Liabilities and Stockholders Equity